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IN THE

Supreme Court of the United States

THE UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY, and UNIVERSITY PHYSICIAN ASSOCIATES OF NEW JERSEY,

Petitioners,

v.

DARA CORRIGAN, Acting Inspector General, United States Department of Health and Human Services,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

(1) Whether the Third Circuit erred by interpreting the Inspector General Act of 1978, 5 U.S.C. app. 3 §§ 1-12, to grant the Inspector General of a federal executive agency authority to conduct routine compliance audits of private persons regulated by the agency, in conflict with the unanimous decisions of the D.C. Circuit and the Fifth Circuit.

(2) Whether the substantive interpretation of the Medicare statute and regulations adopted by the Inspector General of the Department of Health and Human Services is ripe for review where the Inspector General is firmly committed to the interpretation and is applying it in regulatory investigations.

LIST OF PARTIES

The parties to the proceedings before the United States Court of Appeals for the Third Circuit were petitioners The University of Medicine and Dentistry of New Jersey, The Cooper Health System, University Physician Associates of New Jersey, Inc., and respondent Janet Rehnquist, Inspector General, United States Department of Health and Human Services. Dara Corrigan is now Acting Inspector General.

RULE 29.6 STATEMENT

Petitioner University of Medicine and Dentistry of New Jersey ("UMDNJ"), a non-profit corporation, is New Jersey's state university of the health sciences, with three medical schools, one teaching hospital in Newark, and various health-related programs throughout the State. Petitioner University Physician Associates of New Jersey, Inc. is a New Jersey non-profit corporation that bills and collects Medicare payments for faculty members at UMDNJ's New Jersey Medical School in Newark. No publicly held corporation owns 10% or more of the stock of either petitioner.

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The district court's opinion dismissing petitioners' Verified Complaint and directing petitioners to produce subpoenaed documents (Appendix ("Pet. App.") 35a-69a) is not published. The opinion of the Third Circuit (Pet. App. 1a-32a) is published at 347 F.3d 57. The court of appeals' order denying rehearing and rehearing en banc (Pet. App. 33a-34a) is not published.

STATEMENT OF JURISDICTION

The court of appeals entered its opinion on October 17, 2003, and denied rehearing and rehearing en banc on December 18, 2003. Petitioners invoke this Court's jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The Appendix (Pet. App. 72a-86a) reproduces the provisions of the Inspector General Act of 1978, as amended, 5 U.S.C.A. app. 3 §§ 1-12 and of the Medicare Act, 42 U.S.C.A. § 1395, *et seq.*, and regulations, 42 C.F.R. §§ 400, *et seq.*, relevant to this petition.

STATEMENT OF THE CASE

This case is about the statutory division of authority between federal agencies authorized to oversee compliance with regulatory requirements and the independent Offices of the Inspectors General assigned to conduct oversight of the agencies' compliance with their congressional mandate and to investigate program recipients for fraud. In 1996, the Inspector General ("IG") of the Department of Health and Human Services ("HHS") announced a plan to audit the pre-July 1996 Medicare billing of every academic medical center in the country. Petitioners are currently the targets of one of these "Physicians At Teaching Hospitals" ("PATH") audits. They are not under investigation for alleged fraud. Petitioners brought this action for declaratory and injunctive relief to challenge the HHS IG's statutory authority to undertake routine compliance audits, and

to challenge her announced substantive interpretation of the Medicare statute and regulations.

REGULATORY BACKGROUND

A. The Medicare Act

Medicare provides health insurance primarily for elderly and disabled persons in the United States. Congress has delegated responsibility for administering Medicare to the Secretary of HHS (the "Secretary"). 42 U.S.C.A. § 1395(g). In turn, the Secretary has delegated her functions to the Centers for Medicare and Medicaid Services ("CMS"). 42 U.S.C.A. § 1395 *et. seq.*; 42 C.F.R. §§ 400, *et seq.* (2002).[1]

Since Medicare's enactment in 1965, physicians with faculty appointments at medical schools (commonly known as "teaching physicians") have rendered daily care to Medicare patients with the assistance of the residents they supervise. Medicare "Part A" reimburses hospitals for certain institutional costs associated with patient care, including residents' salaries. Medicare "Part B" pays for particular medical services provided to Medicare recipients. Medicare will cover treatment provided by teaching physicians, even if residents are involved in the patient's care, so long as the teaching physician renders "sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought." 42 U.S.C.A. § 1395u(b)(7)(A)(i)(I).

Teaching physicians accept an assignment of the patient's Medicare benefits, and submit claims for those benefits to the "Carriers" under contract with CMS. *See* 42 C.F.R. § 405.802. The Carriers, as agents of HHS, process and pay the bills in accordance with substantive Medicare standards issued by the

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1. Before 2001, CMS was called the Health Care Financing Administration or (even earlier) the Bureau of Health Insurance. For simplicity, petitioner will refer to the agency as "CMS" regardless of the time period.

Secretary. 42 U.S.C.A. § 1395u(a)(1)(A). Patients (or their physician assignees) may appeal Carrier decisions. *See* 42 C.F.R. § 405.801, *et seq.* The Carriers also conduct routine compliance audits of Medicare providers. 42 U.S.C.A. §§ 1395u(a)(1)(A), (C); 42 C.F.R. § 421.200(e). CMS, in turn, periodically audits the Carriers to ensure the reliability of their processes. *See, e.g.*, 42 C.F.R. § 421.201. Within four years of payment of a claim, a Carrier may reopen its decision for "good cause" and adjust a payment that it believes was incorrect or improper. 42 C.F.R. § 405.841(b). Beyond the four-year period, a paid claim may not be reopened unless payment was procured by "fraud or similar fault of the beneficiary or some other person." *See* 42 C.F.R. § 405.841(c)(1). The regulations also provide that a "[c]hange of a legal interpretation or administrative ruling upon which a determination or decision was made shall not be considered as good and sufficient reason for reopening the determination or decision." 42 C.F.R. § 405.850.

B. Inspector General Act of 1978

In the Inspector General Act of 1978 (the "IG Act"), Congress created independent Offices of the Inspector General within various federal administrative agencies. *See* 5 U.S.C. app. 3 § 2. The IGs were established to facilitate "objective inquiries into bureaucratic waste . . . and mismanagement." *NASA v. Fed. Labor Relations Auth.*, 527 U.S. 229, 240 (1999). To preserve the integrity of the IGs, Congress made each IG independent of the administrative control of the agency it was charged with overseeing. *See* 5 U.S.C. app. 3 §§ 9(a)(1) and (2), 11 (2).

The IGs are authorized, *inter alia*, "to provide policy direction for and to conduct, supervise, and coordinate audits and investigations relating to the programs and operations of such establishment," and "to recommend policies for, and to conduct, supervise, or coordinate other activities carried out or financed by such establishment for the purpose of promoting economy and efficiency in the administration of, or preventing

and detecting fraud and abuse in, its programs and operations." 5 U.S.C. app. 3 § 4. To that end, the statute gives IGs the authority to "make such investigations and reports *relating to the administration of the programs and operations of the applicable establishment* as are, in the judgment of the Inspector General, necessary or desirable." 5 U.S.C. app. 3 § 6(a)(2) (emphasis added). The head of the agency may transfer additional responsibilities to the IG if they "are properly related to the functions of the Office and would, if so transferred, further the purposes of this Act," but the agency may not transfer "program operating responsibilities" to the IG. 5 U.S.C. app. 3 § 9(a)(2).

The House Report explained the scope of the IGs' intended role, as distinct from the "program operating responsibilities" that Congress required the agencies to retain for themselves:

> While Inspectors General would have direct responsibility for conducting audits and investigations relating to the efficiency and economy of program operations and the prevention and detection of fraud and abuse in such programs, *they would not have such responsibility for audits and investigations constituting an integral part of the programs involved.* Examples of this would be audits conducted by USDA's Packers and Stockyards Administration in the course of its regulation of livestock marketing and investigations conducted by the Department of Labor as a means of enforcing the Fair Labor Standards Act. In such cases, the Inspector General would have oversight rather than direct responsibility.

H.R. REP. No. 95-584, at 12-13 (1977) (emphasis added).

C. Medicare Billing By Teaching Physicians

From 1969 to December 30, 1992, teaching physicians understood based on Medicare regulations that, except for major or dangerous procedures, a teaching physician need *not* be present with a resident at all times to be reimbursed by Medicare

for physician services. In all but complex and dangerous cases, so long as they were the attending physicians, personally rendered some services to the patient during the hospital stay, and supervised residents' services on other occasions, teaching physicians could bill Medicare.

In 1969, in Intermediary Letter 372 ("I.L. 372"), Pet. App. 87a-88a, CMS interpreted the then-applicable regulations[2] to mean that a teaching physician must "either perform the physician's services . . . or supervise the treatment so as to assure that appropriate services are provided . . . and that the care meets the proper quality level." I.L. 372 required the teaching physician to be physically present only "when a major surgical procedure or a complex or dangerous medical procedure is performed." *Id.*[3]

In 1980, Congress codified the substantive standard of I.L. 372. 42 U.S.C. § 1395u(b)(7) then provided that teaching physicians may be reimbursed if "the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought." In adopting that standard, Congress explained that "teaching physicians should personally perform *or personally supervise* patient services in order to qualify for fee-for-service payment" under Part B. *See* H.R. REP. NO. 96-1167, at 70 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5526, 5583 (emphasis added). CMS adopted new regulations restating that statutory standard, and explaining that teaching physicians may bill Medicare if they "assume[]

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2. *See* 20 C.F.R. § 405.521 (1967) (subsequently recodified at 42 C.F.R. § 405.521).

3. The federal military health care program makes the same interpretation of "personal and identifiable direction;" "[i]t is not necessary that the attending physician be personally present for all services, but the attending physician must be on the provider's premises and available to provide immediate personal assistance and direction if needed." 32 C.F.R. § 199.4(c)(3)(xiii)(A)(2).

and fulfill[] the same responsibilities for this patient as for other paying patients"—as demonstrated by actions such as "[r]eviewing the patient's history and physical examination and personally examining the patient within a reasonable period after admission; confirming or revising diagnosis; determining the course of treatment to be followed; *ensuring that any supervision needed by the interns and residents is furnished*; and making frequent reviews of the patient's progress." 42 C.F.R. § 405.521 (emphasis added).

Over the next two years, however, CMS attempted to re-interpret the billing regulations to impose a strict physical-presence requirement for all services to Medicare patients. CMS ultimately conceded on April 27, 1995 that such an interpretation had not been clearly articulated during the decades that its rules had been in existence, and agreed not to impose such an interpretation until a revised billing rule had been promulgated pursuant to the Administrative Procedures Act (APA). Pet. App. 103a.

On December 8, 1995, the Secretary announced revised billing regulations clearly adopting, for the first time, a strict physical-presence requirement for Medicare billing by teaching physicians. *See* 42 C.F.R. § 415.170 (2002) (standard now requires certain resident services be performed "in the presence of a teaching physician.") The Secretary conceded that a physical-presence requirement for all services had not been clearly articulated previously and "was not applied uniformly by all Medicare carriers." 60 Fed. Reg. 63124, 63137 (Dec. 8, 1995). In recognition of that fact, expressly to give the industry time to adjust, the Secretary made the new rules effective six months later, on July 1, 1996.[4]

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4. Petitioners do not challenge the prospective application of the 1996 regulations.

D. The PATH Audits

In June 1996, the HHS IG announced the PATH initiative as a routine billing review of past Medicare charges by teaching physicians at all 125 academic medical centers in the country. Pet. App. 104a-107a. Despite the earlier contrary interpretations by the Secretary and CMS (and the language of I.L. 372), the HHS IG interpreted the *pre-1996* billing regulation to require that a teaching physician have been present "at the elbow" of the resident for all services, complex or minor.

The IG's interpretation was vigorously disputed by the academic medical community, and the Secretary asked the General Counsel of HHS to determine the correct standard. On July 11, 1997, the General Counsel sent a letter (the "Rabb Letter") to the President of the Association of American Medical Colleges and the Executive Vice President of the American Medical Association explaining the terms of an agreement with the HHS IG. Pet. App. 9a. The Rabb Letter conceded that "the standards for paying teaching physicians under Part B of Medicare have not been consistently and clearly articulated by [CMS] over a period of decades," Pet. App. 9a, and that accordingly the IG agreed to undertake PATH audits only when a hospital's Carrier had provided clear written guidance advising that the teaching physician must be physically present for all procedures. *Id.* at 9a-10a.

By letter dated November 4, 1996, the IG served notice to petitioners of her intention to subject them to PATH audits. The IG has taken the position that certain documents mentioned in Carrier indices would (if petitioners had located and read them) have supplied the clear "written guidance" required by the Rabb Letter. On a motion to dismiss, petitioners' verified allegation of not having received such clear guidance must be accepted as true.[5]

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5. While the district court improperly concluded otherwise, the government effectively conceded in the court of appeals that petitioners had not received actual guidance. *See* Brief for Appellee 32-33.

THE PROCEEDINGS BELOW

On October 27, 1999, petitioners filed a Verified Complaint seeking declaratory and injunctive relief against the IG's PATH audit. Petitioners contended that the IG lacks statutory authority to audit simply to determine whether there has been compliance with regulatory requirements—and must instead confine herself to oversight investigations of the agency itself, or investigations into suspected fraud and abuse. Petitioners also challenged the IG's retroactive re-interpretation of the teaching physician billing standard on statutory, due process, and APA grounds.

The IG moved to dismiss the complaint for lack of subject matter jurisdiction, failure to state a claim, and lack of ripeness. To begin the audits, the IG also moved to enforce administrative documents subpoenas served on petitioners after the action started. Petitioners opposed both motions and moved for partial summary judgment.

On January 21, 2003, the District Court granted the IG's motion to dismiss the complaint and her cross-motion to enforce the subpoenas. The District Court implicitly held, without analysis, that the IG has authority to conduct routine compliance audits. Pet. App. 56a. It dismissed petitioners' due process and fair-warning claims for failure to state a claim, finding that petitioners had in fact received the requisite notice of the agency's "new interpretation" of the standard. *Id.* at 58a-62a. And the court held that it lacked jurisdiction under the APA to decide whether the IG's standard was contrary to the Medicare regulations, because the necessary criteria of final agency action and absence of other adequate legal remedy were lacking. *Id.* at 52a-53a. Finally, finding that the IG's actions were "committed to agency discretion by law," *id.* at 55a, and that the case is not ripe for judicial review, *id.* at 57a, the court declined "to exercise . . . discretion at this time" under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202 (1988). *Id.* at 58a. The court did not rule on petitioners' cross-motion

for summary judgment, finding it moot in view of its previous rulings. *Id.* at 68a.

Acknowledging petitioners had raised "profoundly serious questions about the wisdom and fairness of PATH audits," Pet. App. 30a, the Third Circuit nonetheless affirmed. The court stated that "[w]hile a primary purpose of the inspectors general is to investigate the operations of their federal departments internally, they are charged with preventing fraud and abuse in the programs of their departments as well." *Id.* at 17a. The Third Circuit reasoned that because petitioners "receive federal funds," they are "not merely regulated by HHS, they are a part of the Medicare program." *Id.* at 17a (citations omitted). In essence, doctors and hospitals (and presumably patients as well) receiving any Medicare reimbursement thereby become *a part of HHS*—and hence subject to IG oversight no less than the agency's regular employees.

The Third Circuit acknowledged petitioners' argument that "in the absence of a specific allegation of fraud," the PATH audits are "simply a routine matter of ensuring compliance with the regulations, a responsibility central to the basic mission of HHS itself." *Id.* at 18a. But the court apparently concluded that the IG Act imposes no limitations on an IG's authority to conduct routine regulatory compliance audits, so long as the agency retains authority to conduct such audits as well. "If the [agency] fails to perform a function that is within its responsibilities, and the inspector general takes on those responsibilities, then it may be correct to speak of 'transfer' of program operating responsibilities" prohibited by § 9(a)(2) of the IG Act. *Id.* at 19a. But if the agency retains the right to perform such audits itself, the court wrote, "we see no basis for concluding that the inspector general's authority cannot overlap with that of the [agency]." *Id.* at 18a. The court discussed only the § 9(a)(2) prohibition on additional transfers of responsibility to the IG (even though no party has contended that such a transfer has occurred here), and did not analyze whether routine compliance audits fall within the IG's statutory authority under § 6 (to

conduct "investigations . . . relating to the administration of the programs and operations of the [agency] . . .").

The Third Circuit recognized that the D.C. Circuit's decision in *Truckers United for Safety v. Mead*, 251 F.3d 183 (D.C. Cir. 2001), is a "seemingly contrary" ruling. Pet. App. 20a. The Third Circuit distinguished that case upon the ground the IG "merely lent his search and seizure authority to [the agency's] investigations." *Id.* at 20a (quoting *Truckers United*, 251 F.3d at 189).

The Third Circuit also held that neither the IG's decision to open a PATH audit nor its announced substantive interpretation of the teaching physician billing regulations are final agency action subject to judicial review. The court held that petitioners may not challenge the IG's interpretation until after the IG conducts an audit and actually brings an enforcement action against them. *Id.* at 23a-25a.

Petitioners' petition for rehearing and rehearing en banc was denied on December 18, 2003, Pet. App. 70a-71a.

REASONS FOR GRANTING THE PETITION

This petition should be granted to resolve a split among the courts of appeals concerning the fundamental division of authority between the independent Inspectors General and the federal agencies they are assigned to monitor and investigate. Congress created the IGs to be independent watchdogs over the agencies, not to duplicate the agencies' own core enforcement responsibilities. The Third Circuit ruling essentially grants HHS IG unlimited discretion to assume responsibility for interpreting and enforcing the Medicare statute against the regulated public. That holding directly conflicts with the language and structure of the IG Act and with unanimous decisions of the D.C. Circuit and the Fifth Circuit—both of which have held that IGs lack statutory authority to conduct routine regulatory compliance audits like the PATH audits.

This Court should also correct the Third Circuit's holding that regulated parties may not challenge an agency's announced interpretation of law until the agency actually brings an enforcement action against them. That holding is contrary to this Court's settled precedents, which permit pre-enforcement challenges whenever an agency's legal interpretation will have a direct and immediate effect on the claimant, the agency is prepared to enforce its view, and the balance of hardships favors immediate judicial review. *See Abbott Labs. v. Gardner*, 387 U.S. 136 (1967), *overruled on other grounds*, *Califano v. Sanders*, 430 U.S. 99 (1977); *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990).

I. THE THIRD CIRCUIT'S HOLDING IS INCONSISTENT WITH THE INSPECTOR GENERAL ACT AND THE MEDICARE ACT

The Third Circuit held that the IG Act imposes essentially no constraints on the authority of the HHS IG, except that she may not take over any "program operating responsibilities" of HHS to the complete exclusion of the agency itself. That holding rests on several fundamental errors that, left uncorrected, will defeat the entire purpose of the IG Act by destroying the separation of powers and responsibilities that Congress sought to achieve.

Congress passed the IG Act in response to allegations of widespread corruption, waste and fraud within federal agencies and among their contractors and grantees. S. REP. NO. 95-1071 (1978), *reprinted in* 1978 U.S.C.A.A.N. 2676. Congress believed that uncovering such corruption and fraud required a truly independent investigative body that would not report to the officials responsible for implementing the programs under investigation. *Id.* at 5-6; H.R. REP. NO. 95-584, at 5 (1977). It thus instructed the IGs to investigate and report on the "programs and operations" of their agencies, with a special eye toward "promoting economy and efficiency in the administration

of, or preventing and detecting fraud and abuse in, [those] programs and operations." 5 U.S.C. app. 3 § 4.

The legislative history confirms what is apparent on the face of the statute: these provisions were carefully designed to ensure that the IGs would remain focused on uncovering corruption and fraud within the agency and its programs, and would not simply co-opt or duplicate the agency's own responsibility to interpret and enforce the law against the regulated public. The House Report explains that "[w]hile Inspectors General would have direct responsibility for conducting audits and investigations relating to the efficiency and economy of program operations and the prevention and detection of fraud and abuse in such programs, *they would not have such responsibility for audits and investigations constituting an integral part of the programs involved.*" H.R. REP. NO. 95-584, at 12-13 (1977) (emphasis added). "In such cases, the Inspector General would have oversight rather than direct responsibility." *Id.* As Congressman Levitas explained,

> [t]he Inspectors General will be responsible for audits and investigations only. . . . Moreover, the Offices of Inspector General would not be a new 'layer of bureaucracy' to plague the public. They would deal exclusively with the internal operations of the departments and agencies. Their public contact would only be for the beneficial and needed purpose of receiving complaints about problems with agency administration and in the investigation of fraud and abuse by those persons who are misusing or stealing taxpayer dollars.

124 Cong. Rec. 10,405 (1978).[6]

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6. Representative Levitas's remarks serve as "an authoritative guide to the [IG Act's] construction". *See Adair v. Rose Law Firm*, 867 F. Supp. 1111, 1116 (D.D.C. 1994) (quoting *North Haven Bd. of Educ. v. Bell*, 456 U.S. 512, 526-527 (1982)).

In 1989, the Office of Legal Counsel ("OLC") was asked to mediate a dispute between the Solicitor and the Inspector General in the Department of Labor concerning the scope of the IG's authority.[7] After studying the text and history of the IG Act, OLC concluded that the IG lacked authority to undertake audits or investigations "constituting an integral part of the programs involved." *Id.* at *13-*16. OLC emphasized that permitting the IGs to undertake ordinary "regulatory" investigations "would have constituted a fundamental alteration in the departments' regulatory authority" because it "would have taken away the power to control the investigatory portion of a department's regulatory policy from the official designated by statute or by the Secretary and placed it in an official separate from the regulatory division of the department." *Id.* at *13. "As the legislative history makes clear, however, it was not the intention of Congress to make such a fundamental change in the regulatory structure of the departments and agencies of the federal government." *Id.* Instead, "Congress was concerned with waste of federal funds and the need for an independent official who could review the employees and operations of federal agencies." *Id.*

OLC pointed out that a prohibition on ordinary regulatory investigations "is also dictated by the nature of the Inspector General's role." *Id.* at *14. "One of the Inspector General's functions is to criticize regulatory investigative policy, a function he cannot perform if it is his responsibility to set and implement that policy." *Id.* Furthermore, "[t]he purpose of the Act is not only to protect the taxpayers' money, but also to serve as a check on mistreatment or abuse of the general public by government employees." *Id.* at *15. If the IG conducts regulatory investigations herself, "the very evil that Congress wanted to avoid by establishing an objective Inspector General would be

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7. In so doing, however, OLC made its opinion applicable to all inspectors general. Authority of the Inspector General to Conduct Regulatory Investigations (Preliminary Opinion), 13 Op. O.L.C. 63, 1989 OLC LEXIS 4, at *4 n.3 (March 9, 1989).

created: namely, the responsible official would be charged with auditing and investigating his own office." *Id.*

OLC concluded that "the legislative history and structure of the Act provides compelling evidence that in granting the Inspector General authority to 'conduct and supervise audits and investigations relating to programs and operations'" of the agency, "Congress did not intend to grant the Inspector General authority to conduct, in the words of the House Report, 'investigations constituting an integral part of the programs involved.'" *Id.* at *16. "Rather, the Inspector General's authority with respect to investigations pursuant to the Department's regulatory statutes is, again in the words of the House Report, one of 'oversight.'" *Id.*

Routine billing compliance audits like the PATH audits are clearly "investigations constituting an integral part of" the Medicare program itself. Congress expressly assigned responsibility for such audits to the Secretary, and instructed the Secretary to impose on private contractors acting as her agents (the "Carriers"), the obligation to perform them in the first instance. 42 U.S.C.A. § 1395 u(a)(1)(A)(C). For thirty years the Carriers have been doing precisely that. It has always been understood that Carriers are to "conduct a variety of reviews to determine the appropriateness of payments even when there is no evidence of fraud."[8] The Secretary or a Carrier can seek to recoup Medicare overpayments revealed by such audits,[9] although the statute and regulations impose important

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8. *See* Medicare Program Integrity Manual ("PIM"), *available at* http://www.cms.gov/manuals/ 108__pim/ pim83toc.asp, Ch. 2 § 3.4 (Rev. 16, 11-28-01) (Centers for Medicare & Medicaid Servs.). The statute and regulations in turn require CMS to audit the *Carriers'* performance. *See, e.g.*, 42 C.F.R. § 421.201.

9. The Secretary can recover overpayments in an administrative recoupment proceeding, 42 U.S.C.A. § 1395gg(b); 42 C.F.R. § 405.841, and a carrier can also recover overpayments in accordance with CMS regulations. 42 C.F.R. § 421.200(i).

restrictions and time limits.[10] When Carriers suspect fraud, they are required by CMS under the PIM chapter 3 criteria to make a referral to the IG for a fraud investigation. *See* PIM, Ch. 1 § 3 (Rev. 3, 11-22-00) ("All cases of potential fraud are referred to the OIG."). But routine compliance audits are assigned, by statute, to the Carriers themselves.

Petitioners' Carrier has conducted those audits, has concluded that petitioners' billing practices are consistent with the law, and has never referred any suspicion of fraud or abuse to the IG for investigation. It is undisputed that the IG herself has no reason to suspect fraud by petitioners.[11] The PATH audit initiative was launched as a review of the past billings of every academic medical center in the country, without regard to any particularized suspicion of fraud or abuse. Its principal stated objective is to assess compliance with the Secretary's pre-1996 teaching-physician billing standard—as interpreted by the IG. Such routine compliance reviews are an integral part of the Medicare program; indeed, the IG herself has characterized compliance audits as "part of the fabric of routine hospital operations." Notices, Publication of the OIG Compliance Program Guidance for Hospitals, 63 FED. REG. 8987, 8988 (Feb. 23, 1998). The IG's decision to conduct such audits herself turns the IG Act on its head.

The Third Circuit's contrary conclusion rests on two critical errors. First, the Third Circuit held that there had been no "transfer" of "program operating responsibilities" prohibited by

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10. After four years the Carrier's determination may be reopened only upon a showing of "fraud or similar fault of the beneficiary or some other person." 42 C.F.R. § 405.841(c)(1). And a "[c]hange of a legal interpretation or administrative ruling upon which a determination or decision was made shall not be considered as good and sufficient reason for reopening the determination or decision." 42 C.F.R. § 405.850.

11. Paragraph 73 of the Complaint alleged that the "IG told plaintiffs that she has no evidence of fraud at plaintiffs' institutions." On a motion to dismiss, petitioners' allegations must be assumed to be true.

§ 9(a)(2) because the Secretary and the Carriers have not surrendered the authority to conduct such audits themselves. As to the PATH audits, that misses the point. True, the IG does not contend that any formal transfer of authority has taken place. The point is that such a transfer, *even if it had occurred*, would have been invalid under 9(a)(2), which bars such transfer by the Secretary. Here, the HHS IG has exceeded her limited jurisdiction under §§ 2, 4, and 6 of the Act. Instead of confining its role to independently monitoring the agency's fulfillment of its program responsibilities, HHS IG has unilaterally assumed program operating responsibilities, while the agency has, *de facto*, permitted an IG audit to substitute for its own oversight of 125 teaching hospitals. The HHS IG is thus exercising agency "program operating responsibilities" in a manner that would violate Section 9(a)(2) if a transfer had occurred; for the same reason, HHS IG has exceeded its jurisdiction.

Second, the Third Circuit held that because petitioners "receive federal funds," they are "not merely regulated by HHS, they are a part of the Medicare program" and hence "within the range of legitimate targets of the inspector general's efforts 'to prevent and detect fraud and abuse' in the Medicare program." Pet. App. 17a (citations omitted). That maneuver eviscerates the IG Act in the Medicare/Medicaid context—and for any other federal programs, such as Veterans' Affairs or Social Security, that exist principally to distribute federal benefits. If the hospitals, doctors, and patients receiving benefits through Medicare are all "a part of the Medicare program," then the IG Act's fundamental distinction between the agency's regulatory jurisdiction and the IG's "oversight" jurisdiction becomes nonsensical. In the Third Circuit's view, there is no regulated public; all interested parties are a part of the agency itself, and thus subject to oversight by the IG. That is plainly not what Congress intended.

While the OLC opinion does suggest that the IGs are permitted to investigate an agency's "employees, contractors, grantees and other recipients of federal funds," OLC op. at *2

n.1 (emphasis added), OLC was there addressing fraud investigations and was clearly not considering a situation in which the entire regulated public technically receives federal funds—and plainly would not have countenanced an interpretation of that language that rendered the rest of its carefully reasoned opinion a nullity. And although OLC specifically declined to address the implications of its opinion in the HHS context, it did specifically reject the HHS IG's suggestion (raised in a memorandum to OLC) "that Section 9(a)(2) provides authority to delegate the conduct of regulatory investigations to the Inspector General of Health and Human Services." *See* OLC op. at *16 n.13.

II. THE THIRD CIRCUIT'S HOLDING CONFLICTS WITH SETTLED PRECEDENT OF THE D.C. CIRCUIT AND THE FIFTH CIRCUIT

The Third Circuit's holding directly conflicts with the settled precedent of the D.C. Circuit and of the Fifth Circuit. The Third Circuit acknowledged the apparent conflict with the D.C. Circuit's opinion in *Truckers United*, but attempted to distinguish it on implausible grounds. The Third Circuit also cited the Fifth Circuit's decisions in *Burlington Northern Railroad Co. v. Office of Inspector General*, 983 F.2d 631 (5th Cir. 1993), and *Winters Ranch Partnership v. Viadero*, 123 F.3d 327 (5th Cir. 1997), but failed to recognize that its decision conflicts with those precedents.

The facts of *Truckers United* were remarkably similar to this case. Under the Motor Carrier Safety Act of 1984, Pub L. No. 98-554, 98 Stat. 2829 (1984), the Secretary of the DOT has authority to issue regulations governing vehicle safety and to investigate motor carriers' compliance with those regulations. 49 U.S.C. §§ 502(a), 504(c)(1)-(2). The Secretary of DOT delegated that authority to the Federal Highway Administration ("FHA"), which in turn delegated it to the Office of Motor Carriers ("OMC"). OMC and the DOT-IG embarked on a program "to combine the efforts of OIG and OMC staffs in a

joint investigative review of specific motor carriers to create a greater deterrence to motor carrier violations of the . . . [s]afety [r]egulations." *Truckers United*, 251 F.3d at 187. An association of motor carriers challenged the DOT-IG's participation in such investigations, and sought the return of records and other property seized by the DOT IG.

The D.C. Circuit held that the IG Act prohibits an IG from conducting "investigations that are at the heart of an agency's general compliance enforcement responsibilities." *Id.* at 185. It acknowledged that "[t]he IG has authority to investigate the DOT's administration of programs and operations," and that "'honest cooperation' between the IG and agency personnel can be expected." *Id.* at 189 (citation omitted). "The IG, however, is not authorized to conduct investigations as part of enforcing motor carrier safety regulations—a role which is central to the basic operations of the agency." *Id.* The court emphasized that

> the DOT IG involved himself in a routine agency investigation that was designed to determine whether individual trucking companies were complying with federal motor carrier safety regulations. This was beyond his authority.

Id. The D.C. Circuit held that the IG's investigation was "*ultra vires*," and ordered that the seized property be returned. *Id.* at 190.

The PATH audits are similarly "designed to determine whether individual [providers] were complying with federal [Medicare billing requirements]," intruding on "a role which is central to the basic operations of [HHS]." *Id.* at 189. Petitioners plainly would have prevailed in the D.C. Circuit if this case had been filed there.[12]

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12. Congress has granted different, and in some cases broader, statutory authority to particular IGs. One such grant to the DOT IG might change the result in *Truckers United* discussed above if it arose again. *See Truckers United*, 251 F.3d at 185 (discussing Motor Carrier Safety (Cont'd)

The Third Circuit acknowledged an apparent conflict with *Truckers United*, but attempted to distinguish it on the ground that the IG in *Truckers United* "was not engaged in an audit investigation, rather, he 'merely lent his search and seizure authority to standard OMC enforcement investigations.'" Pet. App. 20a (quoting *Truckers United*, 251 F.3d at 189). That distinction will not bear scrutiny. The D.C. Circuit was not concerned with the formality that OMC rather than the DOT-IG had initiated the investigation in question. It characterized the "principal issue" as "whether the IG had authority in 1998 to investigate motor carriers' compliance with safety regulations," 251 F.3d at 189, and concluded that it did not, *id.* The D.C. Circuit held that the DOT-IG could not engage in regulatory compliance investigations—"a role which is central to the basic operations of the agency." *Id.* Nothing in the D.C. Circuit's opinion suggests that the DOT-IG could have conducted such an investigation if it had been acting on its own initiative rather than cooperating with the agency. To the contrary, that purported distinction clearly cuts the other way. If the IG Act forbids a joint compliance audit by the IG and the agency, it surely prohibits the IG from conducting compliance audits unilaterally, thus usurping the agency's function entirely.

In *Burlington Northern*, the Fifth Circuit considered a similar challenge to regulatory compliance investigations being conducted by the Inspector General of the Railroad Retirement Board ("RRB-IG"). The RRB-IG "apparently believed that the IRS's periodic audits of railroad employers—which checked

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(Cont'd)

Improvements Act of 1999, Pub. L. No. 106-159, 113 Stat. 1748 (1999)). Similarly, the IG of the Department of the Interior now performs programmatic audit duties of the former office of the United States Comptrollers for various U.S. territories as a result of another specific grant of authority by Congress. *See* Insular Areas Act, Pub. L. No. 97-357, 96 Stat. 1705 (1982); *see also* 5 U.S.C. app. 3 §§ 8-8G. These statutes demonstrate that Congress understands how to expand the authority of an IG when it sees a need. Congress has not made such transfer to the IG of HHS.

the accuracy of their reporting under the Railroad Retirement Tax Act—even when coupled with the RRB's summary reconciliation procedures—were not adequate for detecting the underpayment of taxes. Accordingly, [he] began auditing the railroad companies himself." 983 F.2d at 635.

The Fifth Circuit held that the RRB-IG exceeded his authority under the IG Act by undertaking tax compliance audits, a function which Congress had delegated to the RRB:

> [W]e hold that an Inspector General lacks statutory authority to conduct, as part of a long-term, continuing plan, regulatory compliance investigations or audits. By 'regulatory compliance investigations or audits,' we mean those investigations or audits which are most appropriately viewed as being within the authority of the agency itself. Thus, as a general rule, when a regulatory statute makes a federal agency responsible for ensuring compliance with its provisions, the Inspector General of that agency will lack the authority to make investigations or conduct audits which are designed to carry out that function directly.

Burlington Northern, 983 F.2d at 642. The Fifth Circuit noted that the RRB-IG "never suggested that he had any reason to suspect that Burlington Northern was engaged in fraudulent or abusive reporting," and upheld the district court's finding that the audit "was designed to ensure tax compliance, with the detection of fraud and abuse being only a by-product." *Id.* at 640.

In *Winters Ranch*, the Fifth Circuit clarified and reaffirmed its interpretation of the IG Act in the course of distinguishing *Burlington*. The IG of the Department of Agriculture was engaged in a "survey program designed to determine whether the agency's procedures for detecting and preventing fraud and abuse were effective and whether deficiencies were prevalent in the agency's price support programs" and "to determine the

scope, patterns, and possible antidotes for the problem" so that he could "make recommendations as to necessary or desirable remedial measures to the head of the agency and to Congress." *Winters Ranch*, 123 F.3d at 333. The IG issued subpoenas to six selected regulated parties in order to "spot check" the agency's audit procedures, and in the process duplicated those audit procedures to a limited extent. The district court held that such duplication necessarily violated the prohibition on transfers of "program operating responsibilities" in § 9(a)(2) of the IG Act.

The Fifth Circuit reversed, but in terms that reaffirm, rather than undermine, *Burlington*. The court explained that nothing in the IG Act "prevents the IG from using investigative techniques similar to the agency's end-of-year reviews as a means of executing the IG's functions." *Id.* at 334. Unlike the investigation considered in *Burlington Northern*, the six *Winters Ranch* "spot checks" were clearly designed to further the IG's proper oversight responsibilities rather than to usurp the agency's primary responsibility for regulatory enforcement. *Id.* at 335-36. *Winters Ranch* found the district court's concern with § 9(a)(2) to be misplaced, but only under the limited circumstances of that case:

> Section 9(a)(2) prohibits the transfer of 'program operating responsibilities,' and not the duplication of functions or the copying of techniques. No transfer of operating responsibility occurs and the IG's independence and objectivity is not compromised when the IG mimics or adapts agency investigatory methods or functions in the course of an independent audit or investigation. In fact, no transfer of function can occur simply because the IG emulates a function normally performed by the agency . . . In order for a transfer of function to occur, the agency would have to relinquish its own performance of that function.

Id. at 334. The Fifth Circuit stressed that the USDA IG had not, as in *Burlington Northern*, adopted "a long-term, continuing

plan to fill a void left by the [agency] in primary agency program administration." *Id.* at 336. Rather, "the purpose of the IG's investigation was to test the effectiveness of the agency's discharge of a program operating responsibility as the [IG] Act authorizes and this court clearly indicated an IG may do in *Burlington Northern*." *Id.* The IG in *Winters Ranch*, then, was auditing the auditors; the IG duplicated some of their work in order to assess the agency's effectiveness, not to take over responsibility for performing it in the first instance.

The PATH audits clearly fail the Fifth Circuit's test as explained in *Burlington Northern* and *Winters Ranch*: "when a regulatory statute makes a federal agency responsible for ensuring compliance with its provisions, the Inspector General of that agency will lack authority to make investigations or conduct audits which are designed to carry out that function directly." *Burlington Northern*, 983 F.2d at 642. The Medicare Act makes CMS and the Carriers "responsible for ensuring compliance with" the Part B billing standards for teaching physicians, and dictates an elaborate administrative audit and appeal process for them to follow. As in *Burlington Northern*, the HHS IG has "never suggested that [s]he had any reason to suspect that [petitioners were] engaged in fraudulent or abusive reporting." *Id.* at 640. Unlike the IG in *Winters Ranch*, the HHS IG is not auditing the auditors (i.e., CMS and the Carriers); these are not "spot checks" designed to evaluate the agency's own audit procedures. Rather, this is "a long-term, continuing plan" to assess compliance by *all* of the 125 regulated academic medical centers nationwide. The HHS IG purports to perform the agency's oversight function directly, by auditing the regulated health care providers' routine compliance with the Medicare regulations. That is the agency's job, not the IG's. The PATH audits are thus precisely the kind of "regulatory compliance investigations or audits" that the Fifth Circuit has held the IGs lack authority to conduct. *Id.* at 642.

The Third Circuit's brief discussion of these Fifth Circuit precedents does nothing to diminish the split of authority

between circuits. The Third Circuit failed to grapple with these holdings; it merely cited *Burlington* for the proposition that no "transfer" of "program operating responsibilities" under § 9 can occur unless the agency abdicates its own responsibility, and *Winters Ranch* for the truism that no such transfer occurs merely because the IG "mimics or adapts agency investigatory functions in the course of an independent audit or investigation." Pet. App. 18a-19a. The question for decision, however, is whether the PATH audits fall within the scope of the oversight and anti-fraud authority granted to the IGs by §§ 2, 4 and 6 of the IG Act—or whether they are instead, in the Fifth Circuit's words, simple "regulatory compliance investigations or audits" that the IGs are not permitted to conduct. *Burlington Northern*, 983 F.2d at 642. The Third Circuit did not discuss the portions of *Burlington Northern* and *Winters Ranch* analyzing that issue.

The PATH audit program embodies many of the dangers that OLC warned about in its 1989 opinion. The HHS IG has initiated a long-term program of regulatory compliance audits that have effectively taken over the "investigatory portion of [HHS's] regulatory policy from the official designated by statute." 13 Op. O.L.C. 63 at *13. Indeed, the HHS IG has usurped not only HHS's enforcement discretion but also its right to interpret what the Medicare Act and its own regulations mean—advancing an extremely aggressive interpretation of those regulations that is inconsistent with HHS's own prior pronouncements. Pet. App. 118a. And HHS IG obviously can no longer fulfill her statutory role of "criticiz[ing] regulatory investigative policy" and "serv[ing] as a check on mistreatment or abuse of the general public by government employees," 13 Op. O.L.C. at *14-*15, since she is herself now enmeshed in both the setting of investigatory priorities and the performance of compliance investigations. Indeed, having moved to the front line of the regulatory process, the IG herself would be, as in this case, the principal subject of mistreatment and abuse complaints from regulated persons.

The Third Circuit's decision in this case cannot be reconciled with the settled law of the D.C. Circuit and the Fifth

Circuit. This conflict is important and merits review by this Court. The proper separation of powers as between federal agencies and their independent Inspectors General is an important issue that arises continually within the government but is seldom litigated. Clear guidance about that line is essential—on the one hand to ensure that accountable agency heads are making fundamental substantive decisions about regulatory interpretation and enforcement priorities, and on the other hand that the independence that Congress considered essential to proper performance of the IGs' role is not compromised, and that regulated parties are not subject to multiple audits using conflicting and inconsistent substantive standards.

III. THE IG'S INTERPRETATION OF THE MEDICARE BILLING REGULATIONS IS RIPE FOR REVIEW

This Court should also correct the Third Circuit's erroneous holding that the IG's interpretation of the teaching physician billing standard is not ripe for review. The Third Circuit's decision in this case is inconsistent with the settled law of this Court and the D.C. Circuit.

This Court explained in *Abbott Laboratories v. Gardner*, 387 U.S. 136, 149 (1967), that whether an agency's legal interpretation is ripe for review prior to actual enforcement proceedings depends on "both the fitness of the issue for judicial decision and the hardship to the parties of withholding court consideration." Agency action is fit for review when (1) it raises "purely legal" issues, (2) it constitutes "final agency action" under § 10 of the APA, 5 U.S.C. § 704, and (3) "the impact of the regulations upon the petitioners is sufficiently direct and immediate as to render the issue appropriate for judicial review at this stage." *Abbott Labs*, 387 U.S. at 149-52.

In *Abbott Labs*, the petitioners challenged regulations of the Food and Drug Administration that required drug manufacturers to print the generic name of the drug, as well as the proprietary name, on all labels and advertising. This Court

concluded that the challenge was fit for review because it raised only the "purely legal issue" of the agency's statutory authority; the regulation was not subject to further administrative revision before compliance with it was expected; and the agency was prepared to enforce its decision immediately. On the "hardship" prong, this Court held that the direct and immediate effect on the day-to-day business of the regulated entities—requiring them to either comply with the regulation or face the risk of serious criminal or civil penalties—outweighed any jurisprudential benefits associated with further delay. *Id.* at 152-54. This Court reasoned that the challenged regulation "puts petitioners in a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate. . . . Either they must comply with every time requirement and incur the costs of changing over their promotional material and labeling or they must follow their present course and risk prosecution." *Id.* at 152 (internal quotations omitted).

The present case satisfies the *Abbott Labs* test. As the Third Circuit recognized, the IG's interpretation of the billing standard presents "a pure question of law that may not require further factual development." Pet. App. 25a-26a; *see also Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457 (2001). The IG has been unflinchingly committed to her "physical presence" interpretation of the regulations for more than six years, has committed it to writing despite contrary earlier views from CMS and the Secretary of HHS (Pet. App. 118a), and is insisting that petitioners immediately submit to costly, disruptive, and time-consuming audits on pain of contempt sanctions to evaluate their compliance with that standard. The IG expects compliance with her interpretation *sooner than immediately*—indeed, retroactively going back a decade.

The balance of hardships also favors immediate judicial review. In addition to the inevitable disruption of petitioners' teaching and patient care missions, the audit itself is estimated to cost more than $1,000,000, some of which will be state funds. Verified Complaint ¶ 76. The validity of the IG's interpretation

will inevitably be litigated at some point, and an earlier resolution could spare petitioners, countless other academic medical centers, and the government itself the expense of conducting audits that may well rest on a false legal premise.[13] And petitioners now face a dilemma very similar to the one posed in *Abbott Labs*: they must submit to an illegitimate audit that violates their due process rights,[14] or refuse to cooperate and face sanctions for their refusal.

There is nothing meaningful on the other side of the ledger. Other than conducting as many audits (and extracting as many settlements from academic medical centers) as possible before her interpretation is struck down, the IG has no legitimate interest in postponing review until after the audits have been completed. The only valid reason for delay, the Third Circuit held, is "the possibility that no enforcement action may be taken" after

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13. The IG's own conduct demonstrates that her creative reinterpretation of the teaching physician billing standard is the only reason to conduct these audits at all. When she is precluded by the Rabb Letter from enforcing that interpretation, she abandons the audits. *See* Sean Martin, Protests Prompt HHS to retool PATH Audits of teaching doctors, Amer. Med. News, July 28, 1997 (16 of 49 institutions dropped from PATH audits as a result of the Rabb Letter). The Third Circuit's comment that "it seems unlikely that the choice of which standard would be applied in assessing the billing data compiled would have a significant effect on the university during the audit," Pet. App. 29a, therefore ignores reality. If the IG cannot apply her new standard, the audit will not happen at all.

14. An administrative agency violates the fair-notice constitutional due process standard where it seeks to apply a new interpretation of a regulation retroactively, even if the new interpretation is a permissible one. *United States v. Chrysler Corp.*, 158 F.3d 1350, 1354 (D.C. Cir. 1998); *General Electric Co. v. EPA*, 53 F.3d 1324, 1328-29 (D.C. Cir. 1995); *Satellite Broad. Co. v. FCC*, 824 F.2d 1, 3 (D.C. Cir. 1987); *Gates & Fox Co. v. Occupational Safety & Health Review Comm'n*, 790 F.2d 154, 156 (D.C. Cir. 1986) (Scalia, C.J.). Since the courts below concluded that petitioners could not challenge the HHS IG standard until after it had been applied against them, petitioners' due process claim was not decided by either the District Court or Third Circuit.

the audit, because "the inspector general may change her mind on one or more issues along the way." Pet. App. 24a-25a. As the facts of the PATH initiative and this litigation demonstrate, that is sheer fantasy. Regardless, there is always a theoretical possibility that an agency will "change its mind." The Third Circuit's reasoning would rule out *all* pre-enforcement challenges to an agency's interpretations of law—a position that cannot be reconciled with *Abbott Labs*.[15]

The Third Circuit's reasoning is also in conflict with the settled precedent of the D.C. Circuit. *See, e.g.*, *General Elec. Co. v. E.P.A.*, 290 *F.3d* 377, 380 (D.C. Cir. 2002) ("If the possibility (indeed, the probability) of future revision in fact could make agency action non-final as a matter of law, then it would be hard to imagine when any agency rule—and particularly one that must be updated periodically to reflect advances in science—would ever be final as a matter of law."); *Mountain States Tel. & Tel. Co. v. FCC*, 939 *F.2d* 1035, 1040 (D.C. Cir. 1991) (finding that an issue is fit for review when the regulatory agency "has not suggested . . . even in its effort to avoid [the court's] present review, that its [newly promulgated rules] are open to modification.").

The Third Circuit held that the IG's decision to initiate an audit is not "final agency action" in the relevant sense because "it is a decision only to investigate, which is by nature a preliminary one," Pet. App. 26a, and because the costs associated with responding to government investigations are simply part

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15. Building on the *Abbott* analysis, this Court has articulated the additional concern that judicial intervention not "inappropriately interfere with further administrative action" by the agency. *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998). Because of the posture of this case, that concern too is not germane here. Present administration of the Part B Medicare payments to teaching physicians cannot possibly be impacted by petitioners' receiving pre-enforcement judicial review because the "rule" now being challenged by petitioners was superseded by the current teaching physician payment regulations (42 C.F.R. § 415.172).

of the "'burden of living under government,'" *id.* at 28a (quoting *FTC v. Standard Oil*, 449 U.S. 232, 244 (1980)). That may be true in some contexts, but here that reasoning is circular and inconsistent with *Abbott Labs*. Whether the particular collateral costs imposed by an agency's announced interpretation of law prior to actual enforcement are an inevitable part of the "burden of living under government"—or instead a good reason for permitting pre-enforcement judicial review of that interpretation—is precisely the question to be decided under the *Abbott Labs* test.

The Third Circuit also erred in holding that the IG's interpretation is not final agency action because "the audit at issue here is directed only at past conduct" and "there is no direct effect on plaintiff's primary conduct." Pet. App. 28a (internal quotes omitted). *Abbott Labs* did not restrict itself to situations in which agency action requires the immediate adjustment of prospective *regulated* conduct. But even if it had, that limitation would not preclude a finding of ripeness where the aggrieved parties are directly threatened by agency action as is the case here. After *Abbott Labs*, this Court enunciated the general rule that agency action is ripe once there has been "some concrete action applying the regulation to the claimant's situation in a fashion that harms or threatens harm." *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990). There could hardly be a more pronounced case of concrete action threatening a regulated entity than an agency issuing it subpoenas. Petitioners have been forced to litigate this matter for nearly four years. They have retained outside auditors and counsel and have expended large sums of money. And they have been presented the choice of either producing documents for an audit by an unauthorized agency using a wrong standard or facing sanctions for contempt. Nor can the seriousness of the threat against these state entities be overestimated. Other institutions have been

audited under the IG's standard. Still others have settled to avoid the threat here posited.[16]

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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16. Indeed, *Cooper Health System*, an independent teaching hospital affiliated with UMDNJ and a party to this action when it was commenced, settled with the IG after the Third Circuit ruling rather than bear the costs of being audited under the wrong standard.

APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT FILED OCTOBER 17, 2003

Filed October 17, 2003

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 03-1268

THE UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY; THE COOPER HEALTH SYSTEM; UNIVERSITY PHYSICIAN ASSOCIATES OF NEW JERSEY, INC.

v.

DANA [sic] CORRIGAN, ACTING INSPECTOR GENERAL, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES*

The University of Medicine and Dentistry of New Jersey; The Cooper Health System; University Physician Associates of New Jersey, Inc.,

Appellants.

*(Pursuant to Rule 43(c), F.R.A.P.)

On Appeal from the United States District Court
for the District of New Jersey
D.C. Civil Action No. 99-cv-05046
(Honorable Harold A. Ackerman)

Appendix A

Argued April 23, 2003

Before: SCIRICA, *Circuit Judge*,**
AMBRO and WEIS, *Circuit Judges*

(Filed: October 17, 2003)

OPINION OF THE COURT

SCIRICA, *Chief Judge.*

This is an action seeking an injunction against a planned Medicare audit of New Jersey teaching hospitals by the inspector general of the Department of Health and Human Services. The District Court held that it did not have standing to consider plaintiffs' claims under the Administrative Procedures Act, 5 U.S.C. § 704, and that plaintiffs failed to state a due process claim. The District Court also granted defendant's motion to enforce subpoenas related to the audit. We will affirm.

I.

A. *Medicare Billing.*

The underlying dispute in this case involves Medicare billing at teaching hospitals. The parties differ on when physicians could bill for work performed by interns and residents under Health and Human Services regulations in effect before July 1996. Plaintiffs contend defendant's

** Judge Scirica began his term as Chief Judge on May 4, 2003.

planned audit of their billing records would use an improper standard and should be enjoined.[1]

The Medicare program is the responsibility of the United States Department of Health and Human Services. Within the department, the program is administered by the Centers for Medicare and Medicaid Services, the successor to the Health Care Financing Administration. The processing of bills submitted by the healthcare providers for particular services rendered has been contracted out to several insurance companies known as "carriers." Because the carriers handle the billing and payment, they have initial responsibility for ensuring compliance with the statutes and regulations governing Medicare billing of individually billable services.[2]

Medicare payments to healthcare providers fall under two categories. Medicare Part A covers general hospital expenses, including residents' and interns' salaries. Part B

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1. Plaintiffs are the University of Medicine and Dentistry of New Jersey and two corporations associated with it: the Cooper Health System, a non-profit corporation that owns and operates a teaching hospital affiliated with the university; and University Physician Associates of New Jersey, Inc., a non-profit corporation that processes bills and Medicare payments for university faculty members. The claims of all parties are based on the proposed audit of the university's teaching hospitals.

2. Payments for other kinds of costs, i.e., not on a fee-for-service basis, are made by "intermediaries"—private entities contracted by HHS for processing payments under Medicare Part A. Like the carriers, their Part B analogues, intermediaries have a certain amount of responsibility for ensuring compliance with Medicare requirements. 42 U.S.C. § 1395h.

covers payments made on a fee-for-service basis, reimbursing direct care by physicians, among other services. Consequently, at teaching hospitals, most services performed by residents are covered under Part A, which reimburses the hospitals for residents' salaries, but does not reimburse them on the basis of particular services they provide. 42 U.S.C. § 1395x(b)(6). Physicians providing care to patients, by contrast, are reimbursed under Part B based on the service performed and in line with reimbursement paid to physicians for services outside of teaching hospitals.

But this distinction is not so easily drawn. Physicians can also bill Medicare for services in which residents and interns participate, so long as the physician is sufficiently involved in the provision of services. The appropriate standard for determining when physicians may bill under Part B for work performed by residents and interns is the subject of the underlying dispute in this case.

In 1968, HHS promulgated regulations for Part B reimbursement of services performed at teaching hospitals. The regulations authorized payment to an "attending physician" for services "of the same character, in terms of the responsibilities to the patient that are assumed and fulfilled, as the services he renders to his other paying patients" if the physician "provides personal and identifiable direction to interns or residents who are participating in the care of his patient." 20 C.F.R. § 405.521 (1968). Notwithstanding, "[i]n the case of major surgical procedures and other complex and dangerous procedures or situations, such personal and identifiable direction must include supervision in person by the attending physician." *Id.*

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In 1980, Congress amended the statute, largely adopting the standard HHS stated in its regulations, but omitting the specific references to surgery and other hazardous procedures. The statute now provides that if a physician "renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought, [and] the services are of the same character as the services the physician furnishes to patients not entitled to benefits under this subchapter," the physician may bill for the services under Part B. 42 U.S.C. § 1395u(b)(7)(A)(i)(I).

HHS's regulations were changed in 1992, but continued to authorize payment to a teaching physician only when the attending physician "furnishes personal and identifiable direction to interns or residents who are participating in the care of the patient." 42 C.F.R. § 405.521(b)(1) (1992). And the regulations continued to require that the physician "personally supervise" the residents and interns in the case of major surgery or other dangerous procedures.

Between 1992 and 1996, the Health Care Financing Administration began to interpret the phrase "furnishes personal and identifiable direction" as requiring the physician to be physically present when and where the resident or intern provides the billed service in order to be eligible for Part B payment. This interpretation led to widespread complaints from healthcare providers, many of whom claimed that it amounted to a change in the regulation. A physician could provide "personal and identifiable direction," it was claimed, without being physically present when the resident performed the billed care. The university contends that in response to

these comments, the Health Care Financing Administration agreed to refrain from imposing such a requirement until there was a new rule clarifying the agency's position.

In December 1995, HHS adopted a new rule governing physicians at teaching hospitals that took effect July 1, 1996. The rule now provides, "If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought." 42 C.F.R. § 415.170.

Because the carriers are initially responsible for enforcing the billing standards, the carriers themselves often issue clarifying instructions to the healthcare providers, furnishing a source of information about Medicare billing requirements in addition to the statute and regulations.

B. *The Inspector General.*

The Office of Inspector General of HHS, along with inspector generalships for other federal administrative agencies and departments, is governed by the Inspector General Act of 1978, 5 U.S.C. App. 3.[3] Offices of Inspector General are designed to be "independent and objective units" separate from their respective departments and agencies. 5 U.S.C. App. 3 § 2. They are directed to "conduct and supervise audits and investigations relating to the programs

3. The inspector general for HHS (then the Department of Health, Education, and Welfare) was created by statute in 1976. Pub L. No. 94- 505. The Inspector General Act is similar In relevant respects to the original statute.

and operations" of their respective agencies. *Id.* Their primary task is to prevent fraud and abuse within such programs and operations. The Office of Inspector General of HHS is thus an independent office with a primary function to investigate fraud and abuse within the Medicare program.

The Inspector General Act grants inspectors general broad discretion to determine which investigations and audits are necessary to its mission, authorizing them "to make such investigations and reports relating to the administration of the programs and operations of the applicable establishment as are, in the judgment of the Inspector General, necessary or desirable." 5 U.S.C. App. 3 § 2.

C. *The PATH Audits.*

The HHS inspector general's auditing of teaching hospitals for overbilling began with an audit of the University of Pennsylvania Health System's Medicare billing records from 1989 to 1994. The audit disclosed three purported deficiencies in the University of Pennsylvania Health System's billing. First, the inspector general reported a substantial amount of billing by physicians for work performed by residents. Second, the audit revealed a certain amount of "upcoding"—billing for procedures more complex than were actually performed. And finally, the inspector general contended that documentation was inadequate for many of the billed items. The University of Pennsylvania Health System paid $30 million to settle any potential False Claims Act charges.

Following that audit, the inspector general (then June Gibbs Brown) decided to expand the investigation to determine if these practices were widespread. The result was the Physicians at Teaching Hospitals ("PATH") initiative, under which the inspector general selected a large number of teaching hospitals nationwide for audits looking for the alleged problems discovered in the University of Pennsylvania audit.

The PATH initiative was launched in 1996, the same year the new HHS regulations expressly adopted a physical presence requirement. PATH audits—including the one now challenged—were directed at billing in the years before the rule change. The operative rules for these audits, therefore, are primarily the rules as amended in 1992, which spoke of "personal and identifiable direction," but did not expressly state that a physician's presence was required. 42 C.F.R. § 404.521(b)(1) (1992).

PATH audits are of two types. "PATH I" audits are those performed by the Office of Inspector General at its expense. A healthcare provider can choose, however, to hire an independent auditor to perform the audit, reporting the results to the inspector general. This is a "PATH II" audit.

A number of healthcare providers and medical professional organizations objected to the initiative, claiming the PATH audits amounted to retroactive application of the 1996 rules. The inspector general contended instead that the rules had always required the physical presence of the physician for Part B payments, even though it was not stated as clearly as under the new rule.

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HHS responded to the controversy by issuing the so-called "Rabb letter." Harriet Rabb, the general counsel of HHS, issued a letter clarifying her views concerning the PATH audits. Rabb, of course, worked for HHS, not the independent Office of Inspector General. Accordingly, her letter is not a policy statement from the Office of Inspector General. Rather, it expressed Rabb's understanding of the standards the Office of Inspector General would apply in determining when a PATH audit would be conducted.

In the letter, Rabb acknowledged that "the standards for paying teaching physicians under Part B of Medicare have not been consistently and clearly articulated by [the Health Care Financing Administration, now the Centers for Medicine [sic] and Medicaid Services] over a period of decades." Letter of Harriet S. Rabb, HHS General Counsel, at 4 (July 11, 1997). Nevertheless, Rabb concluded that the inspector general's interpretation, even if not clearly stated before 1996, was the correct one. Because of the ambiguity, Rabb stated that clear statements by the carriers "would be controlling." *Id.* Thus, if the carriers had issued materials clearly stating a physical presence requirement, the providers would bound [sic] by it. Rabb concluded that many, though not all, carriers had expressly stated that physical presence was required for teaching physicians to receive compensation under Medicare Part B.

Given this, Rabb stated her understanding that carrier notification would be a necessary requirement for initiation of a PATH audit: "[T]he OIG will undertake PATH audits only where carriers, before December 30, 1992, issued clear explanations" that Part B payments would be made only

"when the teaching physicians either personally furnished services to Medicare beneficiaries or were physically present when the services were furnished by interns or residents." *Id.* at 5. An audit would go forward only after the Office of Inspector General had "obtained carrier materials showing that clear instructions on the need for teaching physicians to be physically present were given to the institutions or physicians served by that carrier." *Id.* at 5-6. If the Office of Inspector General obtained such materials, a hospital would "have the opportunity to show, as a matter of fact, that it or the teaching physicians at the institution received guidance from the carrier which the hospital views as contradictory to the standard referenced above." *Id.* at 6.

Importantly, the letter states, "The decision whether clear guidance was given by carriers to teaching hospitals and physicians will be made by OIG. That determination is, necessarily, a fact bound one and will have to be made particularly and in each instance." *Id.*

In short, Rabb—speaking on behalf of HHS, not the inspector general—stated the Office of Inspector General would begin a PATH audit only if it was convinced, after a hospital had an opportunity to respond, that the hospital had received clear instructions from its carrier of the physical presence requirement.

D. *This Case.*

When the Office of Inspector General informed of its intention to initiate a PATH audit, the University of Medicine and Dentistry of New Jersey initially elected to have a PATH

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II audit performed by an independent auditor at its expense. But it never went forward with the audits and instead filed this action to enjoin the audits.

The university contends the audits are unlawful for several reasons. First, it argues the inspector general lacks the power to conduct PATH audits, as they are properly the function of HHS. It also argues the Office of Inspector General did not comply with the terms of the Rabb letter, concluding the University of Medicine and Dentistry was auditable without its having received clear notice from its carrier. And because it lacked prior notice of the standard the Office of Inspector General intends to apply in its audit, the university contends the initiation of the audits is arbitrary and capricious and violates its due process rights.

Because of the university's refusal to go forward with the audit, the inspector general issued administrative subpoenas for the relevant records. The university refused to comply with the subpoenas. Consequently, the inspector general filed a motion to enforce the subpoenas in the District Court.

The District Court rejected the university's claims, primarily on the basis of its finding a lack of subject-matter jurisdiction for lack of finality and ripeness. It also granted the inspector general's motion to enforce the administrative subpoenas. The university appealed.

II.

The university's challenge to the PATH audits comes to us in two forms. First, because the university has resisted the administrative subpoenas issued by the inspector general, the inspector general brought an action seeking enforcement of those subpoenas. The university appeals the District Court's order enforcing the subpoenas. Second, the university seeks injunctive relief against the audits. Under both sets of claims, the university seeks to block the initiation of the PATH audits. But the audits themselves would appear to be an early stage in an investigation that may or may not lead to enforcement actions. Because of this, the District Court determined that review of most of the university's claims was premature. As we discuss, we hold that the District Court lacked jurisdiction to consider these claims at this stage in the proceedings, but that it had jurisdiction over the inspector general's motion to enforce the subpoenas.

A.

With respect to the subpoenas, the District Court found-correctly-that it had jurisdiction to enforce the subpoenas. Under the Inspector General Act, each inspector general "is authorized . . . to require by subpena [sic] the production of all . . . documentary evidence necessary in the performance of the functions assigned by this Act, which subpena, in the case of contumacy or refusal to obey, shall be enforceable by order of any appropriate United States district court." 5 U.S.C. app. § 6(a)(4); see also 28 U.S.C. § 1345 ("[T]he district courts shall have original jurisdiction of all civil actions, suits or proceedings commenced by the United

States, or by any agency or officer thereof expressly authorized to sue by Act of Congress.").

Although orders enforcing, or refusing to quash, subpoenas issued in the trial context are ordinarily not considered final orders subject to appeal (unless a contempt order is entered, which is itself a final order subject to appeal), orders enforcing administrative subpoenas are subject to appellate review. "These orders are considered 'final' for purposes of 28 U.S.C. § 1291 because there is no ongoing judicial proceeding that would be delayed by an appeal." *In re Subpoena Duces Tecum*, 228 F.3d 341, 345-46 (4th Cir. 2000); see also *FDIC v. Wentz*, 55 F.3d 905 (3d Cir. 1995) (reviewing order enforcing administrative subpoena); *NLRB v. Frazier*, 966 F.2d 812, 815 (3d Cir. 1992) (reviewing quashal). "[W]e will affirm an order enforcing an agency's subpoena unless we conclude that the district court has abused its discretion." *Wentz*, 55 F.3d at 908.

B.

As the Supreme Court has said of the Federal Trade Commission and Internal Revenue Service, an agency ordinarily "can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not." *United States v. Powell*, 379 U.S. 48, 57 (1964) (IRS); *United States v. Morton Salt Co.*, 338 U.S. 632, 642-643 (1950) (FTC); *see also Wentz*, 55 F.3d at 908 (FDIC). The power to effectively investigate HHS and the participants in the Medicare program is fundamental to the HHS inspector general's mission. *Cf. Fed. Maritime Comm'n v. Port of Seattle*, 521 F.2d 431 (9th Cir. 1975) ("It is beyond cavil

that the very backbone of an administrative agency's effectiveness in carrying out the congressionally mandated duties of industry regulation is the rapid exercise of the power to investigate the activities of the entities over which it has jurisdiction and the right under the appropriate conditions to have district courts enforce its subpoenas."). In the ordinary course, judicial proceedings are appropriate only after the investigation has led to enforcement, because "[j]udicial supervision of agency decisions to investigate might hopelessly entangle the courts in areas that would prove to be unmanageable and would certainly throw great amounts of sand into the gears of the administrative process." *SEC v. Wheeling-Pittsburgh Steel Corp.*, 648 F.2d 118, 127 n.12 (3d Cir. 1981) (quoting *Dresser Industries, Inc. v. United States*, 596 F.2d 1231, 1235 n.1 (5th Cir. 1979)).

For these reasons, judicial review of administrative subpoenas is "strictly limited." *FTC v. Texaco*, 555 F.2d 862, 871-72 (D.C. Cir. 1977) (en banc). "The ultimate inquiry . . . is whether the enforcement of the administrative subpoena would constitute an abuse of the court's process." *Wheeling-Pittsburgh*, 648 F.2d at 125. A district court should enforce a subpoena if the agency can show "that the investigation will be conducted pursuant to a legitimate purpose, that the inquiry is relevant, that the information demanded is not already within the agency's possession, and that the administrative steps required by the statute have been followed. The demand for information must not be unreasonably broad or burdensome." *Wentz*, 55 F.3d at 908 (citing *Powell*, 379 U.S. at 57-58; *Morton Salt*, 338 U.S. at 652).

C.

The University of Medicine and Dentistry of New Jersey contends the subpoenas were not "issued pursuant to a legitimate purpose" because the inspector general lacks the authority to conduct PATH audits in the absence of evidence of fraud or abuse. And the university avers that the inspector general admitted to them that she had no evidence of Medicare fraud at the university hospitals.

As noted, the Inspector General Act creates Offices of Inspector General "to prevent and detect fraud and abuse in . . . programs and operations" of their respective departments and agencies. 5 U.S.C. App. 3 § 2. To accomplish these ends, the statute specifically authorizes inspectors general "to conduct and supervise audits and investigations relating to [these] programs and operations." *Id.* Furthermore, the Act grants inspectors general a degree of discretion in determining when such audits and investigations are appropriate: "In addition to the authority otherwise provided by this Act, each Inspector General, in carrying out the provisions of the Act, is authorized . . . to make such investigations and reports relating to the administration of the programs and operations of the applicable establishments as are, in the judgment of the Inspector General, necessary or desirable." *Id.* § 6, 6(a)(2).

Here, the inspector general determined that the PATH audits are necessary or desirable for the purposes of preventing and detecting fraud and abuse in teaching hospitals' Medicare Part B billing. Accordingly, at first blush, the PATH audits would seem to fall comfortably within the Inspector General Act's broad grant of authority.

That authority is subject to certain limitations, however. Section 9 of the Act contains a restriction on the ability of the inspectors general to perform program operating responsibilities.[4] The Act permits the transfer of departmental functions that the head of the agency "may determine are properly related to the functions of the Office [of Inspector General] and would, if so transferred, further the purposes of this Act." The Act specifically provides, however, that no such transfer shall include "program operating responsibilities." 5 U.S.C. App. 3 § 9.

The hospitals rely on this section in attempting to establish a distinction between "routine compliance audits" and "fraud investigations." The administration of the Medicare program is the responsibility of HHS (carried out by the Centers for Medicare and Medicaid Services, an agency within HHS). HHS's direct role with respect to Part B payments at teaching hospitals, however, is one of oversight. Most of the direct interaction with the healthcare providers is done by the carriers, who process the bills submitted by the healthcare providers. The carriers are responsible for ensuring, in the first instance, that the bills they receive comply with the statutory and regulatory requirements of the Medicare program, subject to the oversight of the Centers for Medicare and Medicaid Services. Indeed, 42 U.S.C. § 1395u(a) provides that "the Secretary shall to the extent possible enter into . . . contracts [to] . . . make such audits of the records of providers of services as may be necessary to assure that proper payments are made under this part." Thus, HHS, through the carriers, is statutorily responsible for routine compliance audits, which

4. The 1976 Act contained a similar limitation.

are core "program operating responsibilities," according to the university. And because the PATH audits are routine compliance audits, the university contends the authority to conduct them cannot be transferred to the inspector general unless it is acting on a specific allegation of fraud or abuse.

The university does not challenge the inspector general's authority to investigate healthcare providers directly under the right circumstances. While a primary purpose of the inspectors general is to investigate the operations of their federal departments internally, they are charged with preventing fraud and abuse in the programs of their departments as well. The providers are participants in the Medicare program, and through that program they receive federal funds. Thus, they are not merely regulated by HHS, they are part of the Medicare program. As such, they are within the range of legitimate targets of the inspector general's efforts "to prevent and detect fraud and abuse" in the Medicare program. *Cf. Inspector Gen. of the U.S. Dept. of Agric. v. Glenn*, 122 F.3d 1007, 1011 (11th Cir. 1997) ("While we agree that the [Inspector General Act]'s main function is to detect abuse within agencies themselves, the IGA's legislative history indicates that Inspectors General are permitted and expected to investigate public involvement with the programs in certain situations."). The university concedes this, but contends the inspector general's authority to investigate healthcare providers arises only after the inspector general has received a referral from a carrier, or is otherwise responding to a specific allegation of fraud.

If the carriers uncover any evidence that gives rise to a suspicion of fraud on the part of healthcare providers, they are directed to refer the case to the Office of Inspector General for a fraud investigation. Medicare Program Integrity Manual, ch. 3 § 10.1. ("Carriers . . . have a duty to identify cases of suspected fraud and to make referrals of all such cases to the OIG, regardless of dollar thresholds or subject matter."). But in the absence of a specific allegation of fraud, according to the university, an audit is simply a routine matter of ensuring compliance with the regulations, a responsibility central to the basic mission of HHS itself. HHS directs and oversees the carriers' routine auditing of healthcare providers. And because this is routine work performed by HHS (through the carriers), permitting the inspector general to perform such functions would amount to a transfer of "program operating responsibilities."

At bottom, the university contends the inspector general cannot perform such audits because HHS can and does[5] perform those audits in the ordinary course of business. But we see no basis for concluding that the inspector general's authority cannot overlap with that of the department. As the Court of Appeals for the Fifth Circuit stated, "Section 9(a)(2) prohibits the transfer of 'program operating responsibilities,' and not the duplication of functions or the copying of techniques. No transfer of operating responsibility occurs and the IG's independence and objectivity is not compromised

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5. HHS itself does not appear to perform any compliance audits. According to plaintiffs, these are the responsibility of the carriers, acting as contractors for the department. We need not determine what effect, if any, the fact that these audits are not, strictly speaking, functions of the department itself may have on the analysis.

when the IG mimics or adapts agency investigatory methods or functions in the course of an independent audit or investigation." *Winters Ranch Partnership v. Viadero*, 123 F.3d 327, 334 (5th Cir. 1997). The inspector general's mandate to prevent and detect fraud and abuse is not limited by HHS's—or its agents'—own efforts to prevent and detect fraud and abuse.

If the department fails to perform a function that is within its responsibilities, and the inspector general takes on those responsibilities, then it may be correct to speak of "transfer" of program operating responsibilities. *See, e.g., id.* at 334; *Burlington N. R.R. Co. v. Office of Inspector General, R.R. Retirement Bd.*, 983 F.2d 631 (5th Cir. 1993) (finding impermissible transfer of authority where the inspector general audited railroad employers for tax compliance when the board had declined to do so). For in such a case, the department might be said to be abdicating its own responsibilities, which is arguably one of the concerns animating § 9(a)(2)'s prohibition on transfers of program operating responsibilities. But this is not a concern here.

Furthermore, that HHS can and does perform routine compliance audits does not necessarily make them "program operating responsibilities." Routine compliance audits, routine as they be, are nonetheless investigatory in nature, and are directed at enforcing the rules under which the providers operate. They need not be seen as part of the "operation" of the Medicare program. In any event, the statute contemplates the transfer of any duties that may assist the inspector general in its mission, so long as they are not "program operating responsibilities." Presumably, this would

include a range of responsibilities the department might perform, that do not constitute program operating responsibilities. Thus, the fact that the department can and does perform some of these tasks would not alone prevent their transfer to the Office of Inspector General.

The university relies on a seemingly contrary decision reached by the Court of Appeals for the District of Columbia Circuit. In *Truckers United for Safety v. Mead*, 251 F.3d 183 (D.C. Cir. 2001), the court held the Office of Inspector General for the Department of Transportation had overstepped its statutory authority when it engaged in a joint operation with the Office of Motor Carriers (an office within DOT) to investigate trucking records. The program was designed "to create a greater deterrence to motor carrier violations of the Federal Motor Carrier Safety Regulations." *Id.* at 187. The inspector general subpoenaed a variety of records seeking, inter alia, to uncover falsification of hours of service logs.

The court viewed the investigation "as part of enforcing motor carrier safety regulations-a role which is central to the basic operations of the agency." *Id.* at 189. On the court's view, the inspector general was not engaged in an audit investigation, rather, he "merely lent his search and seizure authority to standard OMC enforcement investigations." *Id.* The court concluded that the "actions of the IG were ultra vires." *Id.* at 190.

Here, by contrast, there is no suggestion that the PATH audits are aimed at anything other than the inspector general's (admittedly broad) view of what constitutes fraud and abuse

in the Medicare program. The inspector general is charged with preventing and detecting, by audit and investigation, fraud and abuse in the Medicare program. There is no statutory basis for imposing an additional requirement that the inspector general begin such an audit or investigation only after she has received a referral or other allegation of fraud. And this is especially true given the broad discretion the inspector general enjoys when determining audits and investigations are appropriate.

D.

In sum, the PATH audits are of a kind that is squarely within the broad authority of the inspector general to audit providers for the purpose of preventing fraud and abuse within the Medicare program. The PATH audits do not represent a "transfer" of "program operating responsibilities." The important issue here is not whether the inspector general is doing something that HHS itself (or its agents) might also do, but whether the PATH audits are within the authority granted the inspector general by the Inspector General Act. For the reasons discussed, we hold that they are.

There is no dispute that the subpoenas at issue are relevant to the inspector general's purpose, that the inspector general lacks the information it seeks, that statutory procedures have been followed, or that the demand for information is not unreasonably broad or burdensome. *See Wentz*, 55 F.3d at 908. Consequently, the subpoenas are lawful and we will affirm the District Court's order to enforce them.

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III.

In addition to opposing the inspector general's motion to enforce its subpoenas, the University of Medicine and Dentistry of New Jersey seeks to enjoin the PATH audits for several reasons. The District Court declined to consider the merits of these claims, deciding it lacked jurisdiction over these claims. We agree.

The District Court found a lack of jurisdiction on two related grounds. First, it held it lacked jurisdiction to review the agency action under the Administrative Procedures Act, 5 U.S.C. § 704, because the decision to initiate the audit was not "final." It also concluded, for similar reasons, that the case was not sufficiently "ripe" at this point to permit judicial review.

Ripeness and finality in this context are closely related. Finality is an element in the test for ripeness. *Nat'l Park Hospitality Assoc. v. Dept. of the Interior*, 123 S. Ct. 2026, 2032 (2003); *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967). And as we have noted, "the Court's treatment of the finality issue has involved an inquiry into the broader question of whether a given action is ripe for judicial review." *CEC Energy Co. v. Public Serv. Comm'n*, 891 F.2d 1107, 1110 (3d Cir. 1989). We will address finality within the context of an assessment of ripeness.

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A.

Determining whether a dispute over agency action is ripe involves a two-part inquiry. We must assess "(1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court consideration." *Nat'l Park Hospitality Assoc.*, 123 S. Ct. at 2030; *Abbott Labs.*, 387 U.S. at 149. The fitness question, in turn, requires an assessment of whether the issues presented are "purely legal," whether the agency action is final for purposes of section 10 of the Administrative Procedures Act,[6] and whether "further factual development would 'significantly advance our ability to deal with the legal issues presented.'" *Nat'l Park Hospitality Assoc.*, 123 S. Ct. at 2028 (quoting *Duke Power Co. v. Caroline Envtl. Study Group, Inc.*, 438 U.S. 59 (1978)); *Abbott Labs.*, 387 U.S. at 149.

While there are some factual disputes in this case, the main issue—whether the inspector general has the authority to initiate audits of the providers under the announced standard—is primarily legal. Further factual development does not seem necessary to resolve these issues. But we believe the case is not sufficiently "fit" for judicial review, because the action of the inspector general was not a final one for these purposes.

No matter how decisive the inspector general's determination to initiate a PATH audit of the University of

6. Under section 10(c) of the Administrative Procedures Act, federal courts have jurisdiction to review "final agency action for which there is no other adequate remedy," 5 U.S.C. § 704, unless the action "is committed to agency discretion by law." § 701(a)(2).

Medicine and Dentistry of New Jersey under its stated standard was, it was only a decision to initiate an investigation of the university's prior billing practices. Neither the university nor the other plaintiffs has been charged with fraud, nor has any kind of enforcement proceeding commenced. The hospitals are required neither to change their billing practices nor pay a penalty for past practices. All they are required to do is to cooperate with the audit—an audit the Office of Inspector General would perform at its expense if the university so chose.

Courts should hesitate to scrutinize decisions to initiate administrative audits and investigations for the same reasons they accord administrative entities broad leeway in issuing subpoenas. Subpoenas in this context are part of an investigation or audit, taken after the decision to investigate has been made, where there is a reason to believe the target of the subpoena may not cooperate without a legal requirement. It would be anomalous to demand a greater showing for the initiation of an investigation than is required for the issuance of subpoenas.

"An investigation, even one conducted with an eye to enforcement, is quintessentially non-final as a form of agency action." *Assoc. of Am. Med. Colls. v. United States*, 217 F.3d 770, 781 (9th Cir. 2000). In the ordinary course, an investigation is the beginning of a process that may or may not lead to an ultimate enforcement action. The decision to investigate is normally seen as a *preliminary* step—non-final by definition—leading toward the possibility of a "final action" in the form of an enforcement or other action. That path is highly uncertain. Here, as in most actions, the

possibility that no enforcement action may be taken is real for several reasons, not least of which is that the inspector general may change her mind on one or more issues along the way. "Judicial intervention into the agency process denies the agency an opportunity to correct its own mistakes and to apply its expertise." *FTC v. Standard Oil Co.*, 449 U.S. 232, 242 (1980).

B.

The university nevertheless contends that the initiation of the PATH audits is a final decision under the standards announced by the Supreme Court and this court. Even if the decision to *initiate* the audits is not deemed final, the hospitals argue the decision to employ a *standard* incorporating a physical-presence requirement was itself "final action" subject to judicial review.

We have listed several factors relevant to an assessment of finality in the administrative context, the most important of which for these purposes are "whether the decision represents the agency's definitive position on the question," "whether the decision has the status of law with the expectation of immediate compliance," and "whether the decision has immediate impact on the day-to-day operations of the party seeking review."[7] *CEC Energy*, 891 F.2d at 1110

7. In *CEC Energy*, we provided the following list of relevant factors:

> 1) whether the decision represents the agency's definitive position on the question; 2) whether the

(Cont'd)

(citing *Standard Oil*, 449 U.S. at 239-40; *Solar Turbines, Inc. v. Seif*, 879 F.2d 1073, 1080 (3d Cir. 1989)).

The decision to initiate the PATH audit represents a "definitive position" of the inspector general only in the narrowest sense. The decision is not likely to be reopened, but it is a decision only to investigate, which is by nature a preliminary one. It is the initiation of a process designed to make a determination as to plaintiffs' potential fraud and abuse in the Medicare program. Intermediate decisions made in the course of determining what position will ultimately be taken are not "determinative" in the appropriate sense. As the Court of Appeals for the Ninth Circuit stated:

> [O]n the facts before this court it is an open question whether the PATH audits will actually result in findings of abuse or fraud. . . . OIG could still modify its rather draconian view of the Act's

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(Cont'd)

> decision has the status of law with the expectation of immediate compliance; 3) whether the decision has immediate impact on the day-to-day operations of the party seeking review; 4) whether the decision involves a pure question of law that does not require further factual development; and 5) whether immediate judicial review would speed enforcement of the relevant act.

891 F.2d at 1110.

We recognize the decision involves a pure question of law that may not require further factual development. We have doubts that immediate judicial review would speed enforcement, but would reach the same result even if we concluded it might.

> requirements for Part B billing, and, for any number of reasons, the PATH audits may not reveal significant violations. Even if violations are found there are a panoply of administrative and judicial remedies open to the Secretary and DOJ, at least some of which we might be without jurisdiction review under 42 U.S.C. § 405(h) and [*Shalala v.*] *Illinois Council [on Long Term Care, Inc.*, 529 U.S. 1 (2000)].

Assoc. of Am. Med. Colls., 217 F.3d at 781.

The University of Medicine and Dentistry of New Jersey also contends the decision to initiate the audits "has the status of law with the expectation of immediate compliance," and "has immediate impact on the day-to-day operations of the party seeking review." *CEC Energy*, 891 F.2d at 1110. Instead of focusing on potential enforcement measures, the university contends the burdens of compliance with the audits themselves constitute the relevant effects. The university avers the decision requires that they immediately comply with the audits-a disruptive process it alleges would detract from providing healthcare and would cost over one million dollars.[8]

These burdens, however, are not the kind of burdens that support a finding of finality. In *Standard Oil*, the Supreme

8. This figure appears to be based on an assessment of a PATH II audit, which would be performed by a third party at the university's expense. A PATH I audit, which the university could have chosen, would be performed by the Office of Inspector General at its cost. Accordingly, it appears the university could choose a course substantially less costly than the one it selected.

Court held the FTC's issuance of a complaint was not a final order in the face of a similar contention. The Court noted that the only legal effect of filing the complaint on defendant was the requirement that it participate in the proceeding by responding to the charges against it. The Court stated, "Although this burden certainly is substantial, it is different in kind and legal effect from the burdens attending what heretofore has been considered to be a final action." 449 U.S. at 242. The Court noted that "the expense and annoyance of litigation is part of the social burden of living under government." *Id.* at 244. There is no basis for treating the expense and annoyance of administrative audits and investigations any differently. *See CEC Energy*, 891 F.2d at 1110 (following *Standard Oil* and stating that the obligation to respond to the FTC's inquiries, even if substantial, is not a basis for finding finality). And because the audit at issue here is directed only at past conduct, the only effects plaintiffs will encounter are related to their participation in the investigatory process and actions that might be taken as a result-there is no direct effect on plaintiffs' "primary conduct." *See Nat'l Park Hospitality Assoc.*, 123 S. Ct. at 2031; *Toilet Goods Assn., Inc. v. Gardner*, 387 U.S. 158, 164 (1967).

We are cognizant of the special responsibilities entrusted to healthcare providers and the obstacles they face. The economics of healthcare are at a precarious juncture. Placing additional burdens—financial and otherwise—on already taxed hospitals may have serious consequences for access to healthcare, either by increasing its cost or by diminishing its availability. It is to be hoped that a decision to initiate a PATH audit will be made only after consideration of these

consequences. But these considerations are, in the first instance, ones for the inspector general, who has been charged with uncovering fraud and has been given the authority to determine when audits are appropriate to that end.

Focusing not on the decision to initiate the audit, but to initiate the audit under a particular standard, the lack of finality is even more clear. For it seems unlikely that the choice of which standard would be applied in assessing the billing data compiled would have a significant effect on the university during the audit. The relevant costs would seem to be associated with collecting the data, not applying any particular standard in interpreting it. The only apparent effect from that choice would come if and when it resulted in a conclusion about plaintiffs' compliance with the applicable standards. And as we have seen, we are not now in a position to assess what might or might not happen at the end of this process.

C.

For the foregoing reasons, the present dispute is not sufficiently "fit" for review at this time. Nor have the hospitals shown sufficient "hardship" to support a determination that the case is ripe for judicial consideration. Again, the only significant hardships resulting from the challenged decision are those related to compliance with a request for information reasonably directed at a legitimate purpose of the inspector general. This is a cost that plaintiffs—recipients of Medicare funding—must face as a "burden of living under government." *Standard Oil*, 449 U.S. at 244.

Appendix A

While the hospitals have raised profoundly serious questions about the wisdom and fairness of the PATH audits, the audits are within the broad authority of the inspector general, and any challenges are properly made when they have led to action against the hospitals and their employees, if any. Accordingly, we will affirm the judgment of the District Court.

Appendix A

AMBRO, Circuit Judge, *Concurring*:

The majority decides (1) generally that the Inspector General ("IG") of the federal Department of Health and Human Services ("HHS") has the authority to issue subpoenas in furtherance of an audit of appellants' teaching hospitals in determining compliance with certain Medicare requirements, and (2) specifically that the District Court lacks jurisdiction to enjoin the audit at issue here because the IG's decision merely to investigate by issuing subpoenas was neither final nor ripe for review. I agree as to (1) and concur in the result as to (2).

At the outset is a paradox. If there is no jurisdiction to consider appellants' attempt to block the Medicare audit, how does jurisdiction exist to enforce subpoenas to turn over documents for the audit? Stated conversely, if there is jurisdiction to review the enforcement of administrative subpoenas like those of the IG, should not jurisdiction also exist to review whether an audit (which the subpoenas attempt to implement) is allowed in appellants' case?

The majority handles this conundrum deftly. The IG has the power under the Inspector General Act of 1978 to investigate fraud and abuse involving Medicare. Inherent within its investigatory power is the authority to issue subpoenas. But a subpoena to an entity operating within the Medicare program merely begins an investigation lacking both the finality and ripeness of an enforcement action that may result from the investigation. Thus the general authority for the IG to issue subpoenas is not, for any particular entity, an action alleging noncompliance with Medicare.

But rather than deciding that specific enforcement of the IG's auditing powers is not final nor ripe for review, I simply would rely on 5 U.S.C. § 701(a)(2) of the Administrative Procedures Act ("APA"), which exempts from judicial review "agency action . . . committed to agency discretion by law." As § 6(a)(2) [5 U.S.C. app. 3, § 6(a)(2)] of the Inspector General Act authorizes the IG "to make such investigations . . . relating to the administration of the programs and operations of [HHS] as are, in the judgment of the [IG], necessary or desirable," § 701(a)(2) applies. *Cf. Webster v. Doe*, 486 U.S. 592, 600 (1988).

A True Copy:
Teste:

Clerk of the United States Court of Appeals
for the Third Circuit

APPENDIX B — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT GRANTING MOTION FOR STAY PENDING APPEAL DATED FEBRUARY 3, 2003

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

January 30, 2003
#E-29-E

No. 03-1268

UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY, et al.

v.

JANET REHNQUIST, INSPECTOR GENERAL, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
The University of Medicine and Dentistry of New Jersey; The Cooper Health System; University Physician Associates of New Jersey, Inc., Appellants
(District of New Jersey Civil No. 99-05046)

Present: ROTH and FUENTES, *Circuit Judges*

1) Emergency Motion by Appellants for Stay of District Court Order Pending Appeal;

2) Response by Appellees in Opposition to Emergency Motion by Appellants for Stay of District Court Order Pending Appeal;

Appendix B

3) Reply by Appellants to Response by Appellees to Emergency Motion for Stay of District Court Order Pending Appeal.

s/ Nicole M. Bruno
Nicole M. Bruno
Case Manager (267) 299-4924

An Order is requested by 5:00pm on 2/4/03.

ORDER

The foregoing motion for stay pending appeal is granted. The Clerk is directed to issue an expedited briefing schedule and the appeal will be listed before the next available panel of the court.

Received and Filed
2/3/03
Marcia M. Waldron,
Clerk

By the Court,
s/ [illegible]
Circuit Judge

Dated: FEB 03 2003

APPENDIX C — OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY DATED AND FILED JANUARY 21, 2003

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Case No. 99CIV5046 (HAA)

Henry A. Ajar, Jr.
Department of Justice
Civil Division
901 E Street, N.W. #1056
Washington, D.C. 20004
(202) 616-8475
HA 8087

THE UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY and THE COOPER HEALTH SYSTEM,

Plaintiffs,

v.

JUNE GIBBS BROWN, INSPECTOR GENERAL, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendant.

Hon. Harold Ackerman

Appendix C

ORDER

Upon Defendant's Motion to Dismiss, Plaintiffs' opposition thereto, and for good cause shown, it is hereby

ORDERED that Defendant's motion is hereby GRANTED, and this action is hereby DISMISSED.

Date: Jan 21st, 2003

s/ Harold A. Ackerman
HAROLD A. ACKERMAN
U.S. District Judge

Appendix C

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Case No. 99CIV5046 (HAA)

UNITED STATES OF AMERICA, for The Inspector General of the U.S. Department of Health and Human Services,

Petitioner,

v.

THE UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY, THE COOPER HEALTH SYSTEM, and UNIVERSITY PHYSICIAN ASSOCIATES of NEW JERSEY, INC.

Respondents.

The Honorable Harold Ackerman

ORDER

This matter having come before the Court on a Cross Motion by the United States for Summary Enforcement of Administrative Subpoenas, and the Court having considered petitioner's request, and defendant's opposition, finds that the subject subpoenas to be within the investigatory authority of the Office of Inspector General, reasonably relevant to the inquiry, and not unduly burdensome and broad.

Appendix C

IT IS ORDERED that respondents the University of Medicine and Dentistry of New Jersey, the Cooper Health System, and University Physician Associates of New Jersey, Inc. shall, within five (5) business days of the date of this order, hand deliver or mail via over-night delivery to Thomas Grippe, Department of Health and Human Services, Office of the Inspector General, Office of Audit Services, Jacob K. Javitz Federal Building, 26 Federal Plaza, New York, New York, 10278, the documents requested in the subpoenas that were served on respondents on April 5, 2000.

Dated this 21st day of January 2003.

BY THE COURT:

s/ Harold A. Ackerman
HAROLD A. ACKERMAN
U.S. District Judge

Appendix C

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CIV. NO. 99-5046 (HAA)

THE UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY and THE COOPER HEALTH SYSTEM

Plaintiffs,

— vs —

JUNE GIBBS BROWN, INSPECTOR GENERAL, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendant.

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Susan Cassell
United States Attorney's Office
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Appendix C

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OPINION

ACKERMAN, Senior District Judge:

This matter is before the court on motion of Defendant June Gibbs Brown, Inspector General, United States Department of Health and Human Services ("HHS-IG") to dismiss the complaint of Plaintiffs the University of Medicine and Dentistry of New Jersey ("UMDNJ") and the Cooper Health Service [sic] ("CHS")[1] for lack of subject matter jurisdiction

1. For the sake of simplicity, the court will refer to UMDNJ and CHS collectively as UMDNJ.

and for failure to state a claim, and on cross-motion of Defendant HHS-IG for summary enforcement of administrative subpoenas against UMDNJ and Plaintiff-Intervenor University Physician Associates, Inc., ("UPA"), and on cross-motion of Plaintiffs UMDNJ for partial summary judgment. For the reasons stated below, Defendant's motion to dismiss is GRANTED, Defendant's motion for summary enforcement of subpoenas is GRANTED, and Plaintiffs' cross-motion for partial summary judgment is DENIED.

I. HHS-IG'S MOTION TO DISMISS THE COMPLAINT

A. Background

1. The PATH Audits

Under the Medicare Act, enacted as Title XVIII of the Social Security Act, the government pays for covered medical care provided primarily to eligible aged and disabled persons. *See* Pub. L. No. 89-97 (1965), as amended, codified at 42 U.S.C. §§1395-1395gg. The Medicare Act consists of two main parts, Part A and Part B. Under Medicare Part B, which generally covers medical and other health services, including physicians' services for eligible elderly and disabled patients, 42 U.S.C. §§1395j-1395w-4, faculty members of medical schools who practice at hospitals affiliated with these medical schools ("teaching physicians"are entitled to be paid for their physician services, 42 U.S.C. §1395x(q). Teaching physicians are paid for their services to patients so long as the physician renders "sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the

payment is sought." 42 U.S.C. §1395u(b)(7)(A)(i)(I). Teaching physicians submit their bills to local insurance companies called carriers that, under contract with the Medicare program, process and pay them in accordance with substantive standards issued by the Health Care Financing Administration ("HCFA"), the agency of HHS that administers the Medicare program. 42 U.S.C. §1395u(a)(1)(A). These bills are subject to audit by the carriers. 42 U.S.C. §1395u(a)(1)(C) (carriers shall "make such audits of the records of providers of services as may be necessary to assure that proper payments are made . . ."). Carriers also are authorized to issue statements to health care providers explaining the Medicare requirements. 42 U.S.C. §1395u(a)(3).

Under the Inspector General Act of 1978 (the "IG Act"), the Office of Inspector General of HHS was established as an "independent and objective unit[]" within HHS "to conduct and supervise audits and investigations relating to the programs and operations" of HHS. 5 U.S.C. app. 3 §2. *Accord* §4(a)(1) (citing §11(2)). In carrying out the IG Act, the HHS-IG is authorized "to make such investigations and reports relating to the administration of the programs and operation of HHS as are, in the judgment of the Inspector General, necessary or desirable. . . ." §6(a)(1).

This case arises from an auditing initiative known as the "Physicians at Teaching Hospitals" or "PATH" audits, which is currently being conducted by the HHS-IG. In the PATH audits, the Inspector General examines whether some Medicare Part B claims submitted by hospitals on behalf of teaching physicians may have (a) systematically exaggerated the services performed by the physicians or (b) double-billed

for services for which payment had already been received under Medicare Part A. See Physicians at Teaching Hospitals (PATH) Audits: Hearing Before Subcommittee on Labor, Health and Human Services, Education and Related Agencies of Senate Committee on Appropriations, S. Hrg. Rep. 105-396, 105th Cong., 1st Sess. (1997) ("Hearing") (testimony of Michael Mangano, Principal Deputy Inspector General). Teaching physicians treat their own patients in addition to performing their training duties, and the Medicare statutes have always provided that such services are compensable under Part B so long as they are genuinely "professional services performed by physicians," 42 U.S.C. §1395x(q), and not merely patient services performed "by an intern or resident-in-training." 42 U.S.C. §1395x(b)(3). In 1980 Congress amended the statute, so that a teaching physician who involved interns or residents in the treatment of his or her patients could not characterize his or her work as a Part B physician's service, unless "the physician render[ed] sufficient personal and identifiable physician's services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought." 42 U.S.C. §1395u(b)(7)(A)(i)(I). Congress sought to give effect to its view that physicians should "personally perform or personally supervise patient services in order to qualify for fee-for-service payment" under Part B. H.R. Rep. No. 1167 at 70, *reprinted in* 1980 U.S.C.A.A.N. at 5583. As will be seen below, this phrase "personally perform or personally supervise" has been the cause of much confusion. Nevertheless, failure to comply with the above standard "would, among other things, constitute a false statement or representation of a material fact" in a Medicare claim. *Id.*

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In 1991, the Secretary promulgated new regulations, which went into effect in 1992. 56 Fed. Reg. 59,502 (Nov. 25, 1991). These 1992 rules were in effect during the period under examination in the PATH audits. On December 8, 1995, the Secretary of HHS announced another revised billing regulation pursuant to the procedures of the APA. Those new billing regulations became effective on July 1, 1996. *See* 42 C.F.R. §415.172 (1996).

In 1996 the HHS-IG announced the PATH initiative as a review of Medicare charges by teaching physicians at all academic medical centers. Compl. Exh. O. They provided that a teaching physician could not bill under Part B for services actually performed by an intern or resident unless the teaching physician was the patient's "attending physician" and he "fumishe[d] personal and identifiable direction to interns and residents who [were] participating in the care of the patient." 42 C.F.R. §405.521(b)(1) (1992). According to plaintiffs, up until December 30, 1992, it was widely understood by teaching physicians that, except for cases of major surgery or a complex and dangerous medical procedure, a teaching physician need not be present when the resident is rendering services to Medicare patients to be paid for physician services. Plaintiffs allege that so 'long as the teaching physicians were the attending physicians, personally rendered some services to the patient during the hospital stay, and supervised residents' services on other occasions, they could bill Medicare for their services. Verified Complaint for Declaratory and Injunctive Relief ("Verif. Compl.") ¶¶2-5, 30-32. Defendant disputes this view of the regulations, insisting that its interpretation of the physical presence requirement is based on its reading of the statute,

the legislative history, and interpretations of the regulations issued by HCFA during the relevant time periods, and consistent with an analysis conducted by the General Accounting Office. Def.'s Motion to Dismiss at 9-10.

In November 1996 Plaintiffs received letters from HHS-IG informing them that HHS-IG planned to conduct reviews of Medicare Part B billings by clinical practice groups at hospitals operated by Plaintiffs. *Id.*, ¶¶25, 28. Pursuant to a PATH audit, the HHS-IG intends to examine physician billing at Plaintiffs' hospitals for the twelve month period from July 1, 1995 through June 30, 1996. Declaration of Timothy J. Horgan ("Horgan Decl.") ¶3. The HHS-IG wants to determine whether Medicare may have paid for complex levels of treatment when the patient's medical record demonstrates that a lower level of service was provided, and whether some physicians billed Medicare for services actually performed by an intern or resident. Plaintiffs allege that the direct costs of the PATH audits to them will be over $1 million. *Id.*, ¶76. In addition, Plaintiffs claim that the audits will cause indirect costs, including, "disrupt[ion] [of] plaintiffs' teaching and patient care operation and diver[sion] of physicians' time from patient care to administrative functions." *Id.* Most significantly, for purposes of the motions before the court, Plaintiffs allege that they did not receive any instructions from their carrier before December 30, 1992 that there was a physical presence standard requirement for attending physician billing.

On July 11, 1997, after receiving complaints about the PATH audits, Harriet Rabb, HHS's general counsel, wrote a letter (the "Rabb Letter") addressed to the President of the

Appendix C

Association of American Medical Colleges and the Executive Vice President of the American Medical Association in which she recognized the ambiguous nature of the Medicare Part B reimbursement requirements. Therefore, OIG determined that, during the period under review, the PATH audits would be conducted according to the following standards:

> First, OIG [the Office of Inspector General will undertake PATH audits only where carriers, before December 30, 1992, issued clear explanations of the rules regarding reimbursement for the services of teaching physicians. . . . Second, OIG will not approach a hospital to open PATH discussions unless and until OIG has obtained carrier materials showing that clear instructions on the need for teaching physicians to be physically present were given to the institutions or physicians served by that carrier. . . . Third, a hospital approached by OIG will have the opportunity to show, as a matter of fact, that it or the teaching physicians at the institution received guidance from the carrier which the hospital views as contradictory, to the standard referenced above. . . . *The decision whether clear guidance was given by carriers to teaching hospitals and physicians will be made by OIG. That determination is, necessarily, a fact bound one and will have to be made particularly and in each instance.* (emphasis added).

Rabb Letter at 5-6.

HHS-IG concluded that UMDNJ's carrier had informed it of the requirement that attending physicians be present during patient services billed to Medicare Part B in at least two publications and that therefore the PATH audit should proceed at UMDNJ.

This action followed.

2. The Verified Complaint

Plaintiffs assert four claims. First, Plaintiffs maintain that HHS-IG's PATH audit of Plaintiffs would be conducted contrary to the agency standards publicly announced in the Rabb Letter for such audits, and would thus constitute arbitrary and capricious action violative of the Social Security Act ("SSA") and the Administrative Procedure Act ("APA"). Verif. Compl., ¶¶90-92. Second, Plaintiffs contend that HHS-IG will violate their due process rights by retroactively applying a new interpretation of a billing standard. Verif. Compl, ¶¶79-84. Third, Plaintiffs allege that under the Inspector General Act of 1978 ("IG Act of 1978"), the HHS-IG does not have authority to conduct what it describes as "routine billing audits like the PATH initiative," and thus its attempt to conduct such an audit is unlawful. Verified Compl., ¶¶85-88. Fourth, Plaintiffs claim that in not abiding by its own publicly announced standards to conduct PATH audits, retroactively applying a novel interpretation of the applicable Medicare billing rule, and arbitrarily selecting the audited institutions, HHS-IG is acting in an arbitrary and capricious manner that violates the APA. Verif. Compl., ¶¶93-95.[2]

2. It is not clear to the Court why Plaintiffs chose to plead Counts One and Four separately. Nevertheless, the Court repeats Plaintiffs' allegations here as Plaintiff has pleaded them.

Appendix C

Defendant seeks to dismiss the complaint for lack of subject matter jurisdiction, failure to state a claim on which relief can be granted, and on the grounds that Plaintiffs' claims are not ripe for review.

B. Standard of Review

Once a defendant raises a jurisdictional defense, the burden shifts to the plaintiff to prove that the court has jurisdiction. *See Mellon Bank (East) PSFS v. Farinom*, 960 F.2d 1217, 1223 (3d Cir. 1992). Where there is a factual question about whether a court has jurisdiction, the trial court may examine facts outside the pleadings. *Robinson v. Dalton*, 107 F.3d 1018, 1021 (3d Cir. 1997). On a motion to dismiss for lack of jurisdiction, plaintiff's allegations are not considered presumptively true, and the existence of material disputed facts will not preclude the court from resolving the existence of jurisdiction. *Id.* at 1021.

On a motion to dismiss for failure to state a claim, the court must accept all facts pleaded as true and draw all reasonable inferences in favor of plaintiff. *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384 (3d Cir. 1994). Matters of public record, orders, exhibits to the complaint, and items appearing in the record of the case also may be considered. *Id.* at 1384 n.2.

C. Subject Matter Jurisdiction-Review Under the APA

UMDNJ asserts that this Court has jurisdiction under the APA to review the HHS-IG's decision to undertake a PATH audit at its hospitals. Pl. Mem. In Opp. At 28. The APA

provides for judicial review by a district court in a case brought by a "person suffering legal wrong because of agency action. . . ." 5 U.S.C. §702. Judicial review of agency action is permissible if (1) the agency action is "final," §704, (2) the plaintiff has no other adequate remedy in court," *id.*, and (3) the agency action is not "committed to agency discretion by law." §701(a)(2). All three conditions must be met in order for this court to have jurisdiction under the APA.

The Third Circuit has outlined the factors that should be weighed in making a determination of the finality of an agency's action. These factors include: (1) whether the agency decision represents its definitive position on the question; (2) whether the decision has the status of law with the expectation of immediate compliance; (3) whether the decision has immediate impact on the day-to-day operations of the party seeking review; (4) whether the decision involves a pure question of law that does not require full factual development; and (5) whether immediate judicial review would speed enforcement of the relevant act." *CEC Energy Co., v. Public Ser. Comm'n of the Virgin Islands*, 891 F.2d 1107, 1110 (3d Cir. 1989). In determining whether an agency's action is final for purposes of allowing for judicial review under the APA, "the core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties." *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992). Such an inquiry must consider whether the impact of the agency's action, "is sufficiently direct and immediate and has a direct effect on . . . day-to-day business." *CEC Energy Co.*, 891 F.2d at 1110. Not all decisions that represent an agency's last word on an issue are final for purposes of

review. *Id.* Rather, finality is to be interpreted in a pragmatic way. *Id.* Significantly, a court should not intervene when an agency's decision constitutes no more than a determination that an investigation will commence, which is a mere prerequisite to definitive agency action. *Id.*

Here, Plaintiffs do not even claim that they are seeking judicial review of HHS-IG's decision to "undertake investigations."[3] (Mem. In Op. at 28). Rather, they claim to be seeking judicial review of HHS-IG's far more remote decision to conduct the PATH audits in accordance with the standards it outlined in the Rabb Letter, a decision which has less direct impact on Plaintiffs than HHS-IG's decision to conduct a PATH audit at Plaintiffs' facility in accordance with the terms of that letter. *Id.* In effect, Plaintiffs assert that the mere decision to write and distribute the Rabb Letter constitutes final agency action. Even without weighing the Third Circuit factors outlined above, it is clear on its face that this decision by the HHS-IG does not even remotely approach the aforementioned requirement that the impact of the agency's action be, "sufficiently direct and immediate and ha[ve] a direct effect on . . . day-to-day business." *Franklin*, 505 U.S. at 797. Had HHS-IG merely written the Rabb Letter without initiating a PATH audit at UMDNJ, the letter and any standards outlined therein would have no impact on UMDNJ whatsoever.[4] Plaintiffs' reliance on *Haddon Township Bd. of*

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3. Plaintiffs do challenge HHS-IG's authority to conduct "routine audits."

4. As discussed further below, even though HHS-IG did initiate a PATH audit at UMDNJ, the Rabb Letter still fails to have the requisite impact on Plaintiffs' day-to-day operations.

Educ. v. New Jersey Dept. of Educ., 476 F. Supp. 681, 689 (D.N.J. 1979) in support of this proposition is misplaced. In *Haddon* Township, defendant New Jersey Department of Education ("NJDE") refused to reimburse three small-town Boards of Education for lunches provided to its students, because those students, whose schools lacked cafeterias and lunch rooms, ate their lunches at home. NJDE refused reimbursement and even asked one of the plaintiffs to repay the Department for reimbursed lunches on the grounds that its co-defendant the United States Department of Agriculture ("USDA") took the position that the National School Lunch Act ("NSLA") prohibited reimbursement for take-home meals. Under the NSLA, the USDA typically reimbursed NJDE for some of the meals it had in turn reimbursed for the school boards. A USDA Assistant General Counsel issued a two-page opinion letter analyzing the plaintiffs' lunch program and concluding that it was not eligible for reimbursement. *Id.* at 685. The plaintiffs disagreed and filed suit. The *Haddon* Court determined that the USDA's letter constituted final agency action. In so doing, it observed that, "the relevant considerations [include] . . . whether rights or obligations have been determined or legal consequences will flow from the action." *Id.*, (quoting *Port of Boston Marine Terminal Association v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 91 (1970)). The rights of the plaintiffs had been effectively determined by the USDA letter, which stated that they had no right to reimbursement under the NSLA. The Rabb Letter did not address UMDNJ and did not determine what UMDNJ's rights or obligations were under the physical presence standard, it merely outlined guidelines it would follow in conducting PATH audits. Likewise, though the decision to conduct a PATH audit at UMDNJ is arguably

a consequence that flows from the Rabb Letter, that decision is not a *legal* consequence. *See infra.* The USDA letter constituted an opinion that had a sufficiently direct and immediate impact on the day-to-day operation of the plaintiffs' schools, as it cut off financial reimbursement of the students' lunches. The Rabb Letter, by contrast, had no such direct impact.

Even if Plaintiffs in this case were asserting that the HHS-IG's decision to conduct the PATH audit at UMDNJ in accordance with the Rabb Letter constituted final agency action, this decision itself still fails to meet the APA's finality threshold. In accordance with the five factors outlined above, this Court finds (1) that the decision to investigate does not represent HHS-IG's definitive position on whether or not UMDNJ has violated the physical presence standard requirement for attending physician billing;[5] (2) that the decision to investigate does not have the status of a determination of law with the expectation of immediate compliance but is rather a mere factual inquiry;[6] (3) that the decision to investigate does

5. "The decision to audit the hospital . . . does not represent the definitive position of the agency in this matter. A PATH audit is only the beginning of a process which may or may not end in the agency's decision to pursue, *inter alia*, an action under the FCA. Mere 'reason to believe' that a party has violated some statute is not the final statement of the agency position, but rather, 'represents a threshold determination that further inquiry is not warranted. . . .'" *Temple University v. June Gibbs Brown, Inspector General, Dep't of Health and Human Services*, 2001 WL 185535 at *6 (E.D.Pa. Feb. 23, 2001) (quoting *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 241 (1980)).

6. "While initiating a PATH audit necessarily requires the hospital's immediate compliance, it does not carry quite the same status of law as would lodging an FCA complaint:" *Temple University*, 2001 WL 185535 at *6.

not have an immediate impact on the day-to-day operations of the party seeking review, since it investigates past practices of UMDNJ;[7] (4) that the decision to investigate not only fails to involve "a pure question of law that does not require full factual development" but is in fact itself the very effort to obtain the full factual development necessary to reach the pure question of law;[8] and (5) that immediate judicial review would, if anything, slow enforcement of the relevant act.[9]

Even if HHS-IG's decision to write and issue the Rabb Letter, or its decision to initiate a PATH audit at Plaintiffs' hospital pursuant to the Rabb Letter constitutes "final agency action," review under the APA is still precluded unless "there is no other adequate remedy in a court." 5 U.S.C. §704. Plaintiffs assert that they have no adequate legal remedy because their opportunity for judicial review depends "solely upon the (unreviewable discretion) of the HHS-IG to serve subpoenas and the Attorney General to commence an FCA [False Claims Act] action." Pl. Mem. in Opp. at 30-31. This

7. As the PATH audit is an effort to review past billing records, UMDNJ is, "still able to carry out [its] medical services and provide care to patients. [This] in no way affects the daily operations of plaintiff's member hospitals." *New Jersey Hospital Ass'n v. United States*, 23 F.Supp.2d 497, 501 (D.N.J. 1998). Moreover, courts have held that the disruption that may accompany an audit, or litigation, is to be expected by regulated private entities, and does not rise to the level of impacting day-to-day operations. *See, e.g., FTC v. Standard Oil*, 449 U.S. 232, 244 (1980); *Temple University*, 2001 WL 185535 at *6.

8. *Temple University*, 2001 WL 185535 at *7.

9. *Id.*

statement vis-a-vis the subpoenas is more than just flatly wrong–it is directly contradicted by Plaintiffs' own actions in this case. HHS-IG did, in act, serve subpoenas on Plaintiffs, and Plaintiffs have refused to comply with HHS-IG's subpoenas, forcing HHS-IG to file its Cross-Motion for Summary Enforcement of Administrative Subpoenas. This Cross-Motion is addressed by the court in this very opinion. Plaintiffs' professed belief that to serve such subpoenas is within HHS-IG's "unreviewable discretion" did not prevent them from refusing to comply with those subpoenas and from seeking, in a subsequent legal brief, judicial review of the exercise of this "unreviewable discretion." That strikes this court as an alternative legal remedy.[10] Moreover, should the government decide, pursuant to its factual inquiry, that Plaintiffs ought to be prosecuted under the False Claims Act, Defendant argues that Plaintiffs would in fact have an adequate alternative legal remedy in defending against the FCA charges. For example, Plaintiffs argue that Defendant failed to follow its own standards as outlined in the Rabb Letter, specifically, by initiating a PATH audit at UMDNJ despite the fact that UMDNJ alleges it never received from its carrier any guidance on how to interpret the physician physical presence requirement.[11] Plaintiffs further argue that the Rabb Letter is the equivalent of a legal standard or regulation

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10. Defendant noted that this course of action was available to Plaintiffs as an alternative legal remedy. Reply Brief at 8.

11. Plaintiffs make this assertion in spite of the fact that the Rabb Letter clearly states: "The decision whether clear guidance was given by carriers to teaching hospitals and physicians will be made by OIG. That decision is necessarily a fact bound one and will have to be made particularly and in each instance." Rabb Letter at 6.

which binds HHS-IG to act in accordance with its terms. Plaintiffs' Mem. in Opp. at 19-20. These assertions constitute a defense to claims brought under the False Claims Act and could be asserted in such an action should it arise. Moreover, while Defendant made this argument in its Motion to Dismiss, Plaintiffs chose not to directly address it in their opposition papers. Instead, Plaintiffs assert that the audits themselves would be "costly and disruptive." Plaintiffs' Mem. in Opp. at 2.

In sum, Defendant's argument that Plaintiffs have an adequate alternative legal remedy in opposing enforcement of administrative subpoenas is more than just an argument, it is a matter of fact: it is an alternative remedy that Plaintiffs have already availed themselves of before this court. Likewise, Plaintiffs have an adequate alternative legal remedy in defending against an FCA suit, should Defendant refer the matter to the Attorney General and the Attorney General decide to bring one. Therefore, this court does not have jurisdiction to hear this case under the APA, as Plaintiffs' case fails to meet the requirement that it have no alternative legal remedy at its disposal.

Judicial review under the APA is not available for actions that are "committed to agency discretion by law." 5 U.S.C. §701(a)(2). Jurisdiction will not exist if a "statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Webster v. Doe*, 486 U.S. 592, 599-600 (1988) (citing *Heckler v. Chaney*, 470 U.S . 821, 830 (1985)).

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The HHS-IG is authorized "to make such investigations and reports relating to the administration of the programs and operations of HHS as are, in the judgment of the Inspector General, necessary or desirable. . . ." §6(a)(1). The use of the word "judgment" expressly leaves any investigation to the discretion of the IG. *Temple University*, 2001 WL 185535 at *8. The only limitation on this judgment is that it be "necessary or desirable." *Id.* The language and structure of §6(a)(2) of the Inspector General Act clearly indicate that Congress intended to leave the decision of whether and how to undertake an audit to the discretion of the HHS-IG. *Id.* Plaintiffs' suggestion that the PATH audit is invalid because it is "neither an audit of HCFA nor a fraud audit [but] . . . [r]ather a routine billing audit", Plaintiffs' Mem. In Opp. at 23, is therefore unavailing. Likewise, Plaintiffs' claim that HHS-IG's conduct of the PATH audits is arbitrary and capricious because it decided "not to audit all academic medical centers" is equally unavailing.

C. RIPENESS

Defendant asserts that Plaintiffs' claims are not ripe for review. Motion to Dismiss at 25. In making a ripeness determination, a court must examine "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Laboratories v. Gardner*, 387 U.S. 136, 149 (1967). An agency action is not ripe for review until the controversy has been reduced to "manageable proportions, and its factual components fleshed out by some concrete action applying the regulation to the claimant's situation. . . ." *Lujan v. National Wildlife Federation*, 497 U.S. 871 (1990). A claim is not ripe for review if it rests

upon "contingent events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998). The following factors should be considered in rendering a ripeness determination: (1) whether delayed review would cause hardship to plaintiffs; (2) whether judicial intervention would inappropriately interfere with further administrative action; and (3) whether the courts would benefit from further factual development of the issues presented. Ohio *Forestry Assoc., Inc. v. Sierra Club*, 523 U.S. 726, 733 (1998).

In accordance with the above requirements, the court finds that Plaintiffs' claims are not ripe for review. First, delayed review would not cause hardship to the Plaintiffs as compliance with a government audit is merely a routine cost of doing business as a regulated entity. Second, because the agency's decision as to whether or not to refer UMDNJ to the Attorney General's office for prosecution under the False Claims Act is not only not final but is at best an event contingent upon an attenuated series of antecedent events, judicial intervention would inappropriately interfere with further administrative action. Third, the courts would unquestionably benefit from further factual development. Plaintiffs' resistance to the PATH audits has prevented virtually any factual development of the issues presented. It is worth noting that the claims at issue here were essentially the same claims held to be unripe in *Temple University*, 2001 WL 185535, *Greater New York Hospital Ass'n v. United States*, 1999 WL 1021561 (S.D.N.Y. 1999), and *Ass'n of American Medical Colleges v. United States*, 34 F. Supp. 2d 1187, 1193 (C.D.Ca. 1998).

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D. Subject Matter Jurisdiction-Review Under the Declaratory Judgment Act ("DJA")

Plaintiffs' complaint also seeks declaratory relief. As the Supreme Court has explained:

> The DJA was an authorization, not a command. It gave the federal courts competence to make a declaration of rights, it did not impose a duty to do so. . . . Of course a District Court cannot decline to entertain such an action as a matter of whim or personal disinclination. 'A declaratory judgment, like other forms of equitable relief, should be granted only as a matter of judicial discretion, exercised in the public interest.

Public Affairs Assoc., Inc. v. Rickover, 369 U.S. 111 (1962).

For three reasons, this court declines to exercise this discretion at this time. First, the DJA is not an independent grant of jurisdiction, and, as has already been established, the court does not have jurisdiction over Plaintiffs' APA claims. Second, a declaration will not resolve this controversy as the controversy itself is not ripe for review. Third, the availability of alternative legal remedies for Plaintiffs suggests that declaratory relief would be inappropriate at this time. *See generally United States v. Pennsylvania*, 923 F.2d 1071, 1075 (3d Cir. 1991).

E. Plaintiffs' Due Process Claim

Plaintiffs' due process claim is that the HHS-IG is seeking to apply against them a substantive rule of which they had

no prior notice. Mem. In Opp. at 16. Due process forbids application of a rule against regulated entities where the existing regulations did not provide fair warning of the agency's interpretation. *United States v. Chrysler Corp.*, 158 F.3d 1350, 1354 (D.C. Cir. 1998); *see also General Elec. Co. v. EPA*, 53 F.3d 1324, 1328-29 (D.C. Cir. 1995) ("In the absence of notice–for example, where the regulation is not sufficiently clear to warn a party what is expected of it–an agency may not deprive a party of property by imposing civil or criminal liability." While this is a correct statement of the law, this Court believes it has no application to the case before it for three reasons: (1) the Rabb Letter is not a substantive rule, and therefore application of it to Plaintiffs does not implicate due process concerns; (2) the physical presence requirement, which is a regulation, has not yet been applied against Plaintiffs; and (3) No civil or criminal liability has been imposed upon Plaintiffs, nor have Plaintiffs been deprived of any constitutionally protected property right.

First, the Rabb Letter is not a substantive rule. Substantive rules, also known as legislative rules, "have the force and effect of law" and "substantive legal effect. . . ." *Dia Navigation Co. v. Pomeroy*, 34 F.3d 1255, 1264 (3d Cir. 1994). "If a rule creates rights, assigns duties, imposes obligations, the basic tenor of which is not already outlined in the [statute] itself, then it is substantive." *Id.* A substantive rule must generally be published in the *Federal Register*, and the rulemaking agency must give the public an opportunity to comment upon it. §553(b), (c). Upon issuing a final rule, which must also be published in the *Federal Register*, the agency must then explain its responses to the public comments. §553(c). Certain non-substantive agency rules, including "rules of agency

organization, practice or procedure," need not go through this process. §553(A). Such rules "do not themselves alter the rights or interests of parties," and are exempted from the notice and comment requirement "to ensure that agencies retain latitude in organizing their internal operations." *American Hospital Ass'n v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987).

Moreover, decisions by executive branch officers on how to exercise enforcement discretion are not substantive rules. *Sullivan v. United States*, 348 U.S. 170 (1954) (affirming conviction on the ground that even though prosecutor had not received prior authorization from Attorney General to present evidence to grand jury, the DOJ directive requiring prior authorization was non-binding). Likewise, a manual provision that "maps out an enforcement strategy" for agency contractors constitutes a procedural rule which is not subject to notice and comment. *American Hospital Association*, 834 F.2d at 1049-50. HHS-IG's discretionary decision to conduct PATH audits in accordance with the Rabb Letter, which explicitly states that the ultimate determination of whether or not the hospitals received guidelines from their carriers will be made by HHS-IG, is not a substantive rule. Therefore, whether or not it has been properly applied to Plaintiffs does not implicate due process concerns.

Second, as has been elaborated upon earlier in this opinion, HHS-IG's effort to conduct an audit of UMDNJ is merely a preliminary step which does not lead inevitably to the conclusion that HHS-IG will seek enforcement of its interpretation of the physical presence requirement against UMDNJ. Consequently, even if Plaintiffs are correct in asserting that,

during the period of time which is subject to the PATH audit, they had no prior notice of the billing requirement that teaching physicians be physically present, no due process concerns have yet been implicated because HHS-IG has not sought enforcement of that requirement against them.

Third, the PATH audits do not implicate any constitutionally protectable property right of Plaintiffs. Plaintiffs' reliance upon *Chrysler Corp.*, 158 F.3d 1350 (D.C. Cir. 1998) is misplaced. In *Chrysler*, the D.C. Circuit reversed the district court decision to grant the National Highway Traffic Safety Administration's ("NHTSA") proposed order of a noncompliance recall of certain Chrysler vehicles. NHTSA argued that a recall order did not raise due process concerns because the D.C. Circuit had only found due process violations in those cases involving "explicit penalties or actions that the Court described as punitive in some manner." *Id.* at 1354. But the D.C. Circuit, pointing out that a recall deprives Chrysler of property no less than a fine, found the recall to be a "sufficiently grave sanction" that had triggered the due process requirement of notice. *Id.* at 1355. Citing *Chrysler*, UMDNJ asserts that its implicated property interest is "the fact that Plaintiffs . . . will incur substantial monetary costs in going through the audits." Mem. in Opp. at 16, n.16. Plaintiffs argue that just as a notice requirement is a protectable property interest of Chrysler, so the costs imposed upon UMDNJ by the HHS-IG's PATH audit constitutes a protectable property interest of UMDNJ. But Plaintiffs have failed to articulate any cognizable property interest that is at stake in such monetary costs imposed by the audit.

In this circuit, the standard for determining whether or not a complainant has a constitutionally protectable property interest is "whether the statute places substantive limits on official discretion for the benefit of the [plaintiff]." *Specter v. Garrets*, 971 F.2d 936, 955 (3d Cir.), *judgment vacated on other grounds*, 506 U.S. 969 (1992). A protectable property interest is created if the statute or regulation confers a benefit on an individual and sets forth "particularized standards or criteria [to] guide the decisionmakers." *Id.*, (quoting *Olim v. Wakinekona*, 461 U.S. 238, 249 (1983). Even if, *arguendo*, the Rabb Letter is considered to be a statute or regulation, it does not bestow a protectable interest upon Plaintiffs because it reserves ultimate discretion over the factual determination as to whether or not auditees received carrier guidelines to HHS-IG itself.

For all of these reasons, Plaintiffs fail to state a due process claim.

II. HHS-IG'S CROSS-MOTION FOR SUMMARY ENFORCEMENT OF SUBPOENAS AND UMDNJ'S CROSS-MOTION FOR SUMMARY JUDGMENT

A. Procedural Background

Also before this court is Defendant's Cross-Motion for Summary Enforcement of Administrative Subpoenas and Plaintiffs' Cross-Motion for Summary Judgment.

On or about April 5, 2000, HHS-IG served administrative subpoenas on Plaintiffs, requesting certain documents in furtherance of "an investigation relating to possible violation

of Title 18, 31 and 42 of the U.S. Code with respect to Medicare, Medicaid, and other Federal health care programs." On April 20, 2000, Plaintiffs wrote to then Magistrate Judge Dennis M. Cavanaugh requesting direction on whether the dispute regarding the subpoenas should be treated as a discovery matter or whether Plaintiffs should file a motion before this Court. On the same date, UPA moved to intervene in this action for the purpose of the subpoena served on it. On April 21, 2000, Plaintiffs advised HHS-IG by letter that they would wait for the Court's decision on the pending motion to dismiss the Complaint before producing the documents in response to the subpoenas.

On April 27, 2000, HHS-IG, in response to Plaintiffs' April 20 letter, advised Magistrate Judge Cavanaugh that it believed that disputes regarding the subpoenas were not a discovery matter and should therefore be presented as a motion to this Court.

On May 8, 2000, HHS-IG responded to UPA's motion to intervene by cross-moving for enforcement of the subpoenas against UPA, UMDNJ and CHA. Plaintiffs consider this cross-motion procedurally defective but have elected to treat HHS-IG's cross-motion against UPA as a motion to enforce the administrative subpoenas against them. In opposing the subpoenas, UMDNJ has also moved for partial summary judgment.

On December, 20, 2002, this Court granted UPA's motion to intervene, and suspended UPA's compliance with the subpoenas until further order of the Court.

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B. LEGAL ANALYSIS

Section 6(a)(4) of the IG Act provides that upon issuance of an IG subpoena, "in the case of contumacy or refusal to obey, [the subpoena] shall be enforceable by order of any appropriate United States district court." The role of the district court in evaluating a request for enforcement "is a strictly limited one," *FTC v. Texaco*, 555 F.2d 862, 871-72 (D.C. Cir. 1977) (en banc) *cert. denied*, 431 U.S. 974 (1977). The sole issue in an enforcement proceeding is whether "the court's process would or would not be abused by enforcement." *SEC v. Wheeling-Pittsburgh Steel Corp.*, 648 F.2d 118, 125 (3d Cir. 1981).

A challenge to the enforcement of an administrative subpoena may be brought upon "any appropriate ground." *Id.* at 124. It is a well-settled legal principle that the federal courts should not use their enforcement machinery merely to rubber stamp investigations. *Id.* Appropriate grounds for challenging enforcement of an administrative subpoena include allegations that an agency is acting in bad faith. *Id.*

Other Courts have recognized that the validity of an agency audit may be challenged in a subpoena enforcement proceeding. *Mobil Exploration & Producing U.S., Inc. v. DOI*, 180 F.3d 1192, 1200 (10th Cir. 1999). Still, where the court determines that "the inquiry is within the authority of the agency, the demand is not too indefinite, and the information sought is reasonably relevant," no abuse of process is present. *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950); see also, e.g., *Oklahoma Press Publishing Co. v. Walling*, 327 U.S. 186, 208 (1946); *United States v. Westinghouse Elec.*

Corp., 788 F.2d 164, 166 (3d Cir. 1986) (applying *Morton Salt* to IG subpoenas); *United* States *v. Aero Mayflower Transit Co.*, 831 F.2d 1142, 1145, 1146 (D.C. Cir. 1987) (same).

> [T]he scope of issues which may be litigated in an enforcement proceeding must be narrow, because of the important governmental interest in the expeditious investigation of possible unlawful activity. . . . [T]he "very backbone of an administrative agency's effectiveness in carrying out the congressionally mandated duties . . . is the rapid exercise of the power to investigate."

FTC v. Texaco, 555 F.2d at 872 (citation omitted).

To determine whether the information sought is reasonably relevant to the agency's inquiry, the enforcing court should also bear in mind that

> administrative investigatory subpoenas must by their very nature be broad. The agency need not narrow its focus from the beginning, and it is not for this court to determine whether the information sought is relevant to whatever eventual action the agency might take. This court may look only to the general purpose of the investigation and determine if the information sought, however broad, is relevant to that purpose.

United States v. Firestone Tire & Rubber Co., 45 F. Supp. 1072, 083 (D.D.C. 1978).

Appendix C

Plaintiffs' arguments that the subpoenas should not be enforced because the underlying PATH audits have been undertaken in an arbitrary and capricious manner in violation of the APA, and that the legal standard HHS-IG seeks to apply in the PATH audits violated the Due Process Clause of the Fifth Amendment of the United States Constitution, are obviously moot as this court has already ruled against Plaintiffs' arguments on those same underlying claims. Plaintiffs also object to summary enforcement of the administrative subpoenas on the grounds that the subpoenas were served in bad faith, and that they are unreasonably burdensome and overbroad.

1. The Subpoenas Were Not Served In Bad Faith

Plaintiffs accuse the HHS-IG of acting in bad faith. "'Bad faith' connotes a decision by an agency to pursue a groundless allegation without hope of proving that allegation . . . or prosecution brought without a reasonable expectation of obtaining a valid conviction." *Wheeling-Pittsburgh*, 648 F.2d at 125-26. Bad faith subpoenas should not be judicially enforced. *United States v. Office Appliance Co., Inc.*, No. 75-166, 1997 U.S. Dist. LEXIS 17608, at *12-13 (D.R.I. Jan 31, 1977); *United States v. McClellan*, No. CV-77-62 U.S. Dist. LEXIS 17944, at *10-11 (D. Mont. May 4, 1978). Such subpoenas implicate the abuse of process standard described above. *United States v. Powell*, 379 U.S. 48, 58 (1964). A subpoena "issued for an improper purpose, such as to harass the [subpoenaed party] or to put pressure on him to settle a collateral dispute, or for any other purpose reflecting on the good faith of the particular investigation" is an example of bad faith. *Id.*

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UMDNJ alleges that HHS-IG has demonstrated bad faith in the declaration of Mr. Timothy Horgan, Regional Inspector General for Audit Services for Region II of the Department of Health and Human Services. UMDNJ argues that the declaration is "deliberately misleading" and that Mr. Horgan "is not a competent witness to testify about significant relevant matters in his affidavit." Plaintiffs Subpoena Opposition ("Pl. Sub. Opp."). This Court finds nothing misleading in Mr. Horgan's affidavit, deliberate or otherwise. It plainly states the HHS-IG's basis for believing that the administrative subpoena is within the authority of the agency, that the demand is not at all indefinite, and that the information sought is reasonably relevant to the inquiry. The affidavit references two documents, a September 1988 Medicare Report and a Medicare Part B Office Training Manual, and provides supporting documentation that quite reasonably leads one to conclude that these documents were in the possession of UMDNJ at the time relevant to the PATH audit. They also happen to raise questions about UMDNJ's underlying contention that they had no notice of the physical presence requirement. At the very least, they establish HHS-IG's good faith basis for issuing the subpoenas. UMDNJ's assessment that Mr. Horgan is not a competent witness is equally baffling. Plaintiffs' statement that, "[a] competent witness on these issues must come from the local carrier" is totally unsupported in its own brief. Mr. Horgan is responsible for audits for providers who receive Medicare in his Region which includes New Jersey, where he has supervisory responsibility over the implementation of the PATH audits. Horgan Decl. ¶1. "Mr. Horgan is not only the ultimate person to authorize a PATH audit, he is the only person who can authorize a PATH audit. . . . [He] necessarily

has knowledge regarding billing guidance sent by the local carrier to plaintiffs." Defendant's Sub. Reply at 6.

Plaintiffs have clearly failed to meet their heavy burden of establishing bad faith on the part of HHS-IG.

2. The Subpoenas Are Not Unreasonably Burdensome or Overbroad

To reiterate the applicable standard, where the court determines that "the inquiry is within the authority of the agency, the demand is not too indefinite, and the information sought is reasonably relevant," no abuse of the Court's process is present. *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950). Plaintiffs' assert that the subpoenas are overly burdensome and overbroad on three grounds. We reject all three. First, where HHS-IG has requested documents that have already been produced, Plaintiffs need only identify them. Defendant's Sub. Reply at 9. Second, it is not for UMDNJ to determine which documents are necessary for a PATH audit. Third, though the production of documents may well place some burden on Plaintiffs, they have failed to demonstrate how compliance with the subpoenas will be "unduly burdensome." *See FTC v. Texaco*, 555 F.2d at 882.

C. UMDNJ's Cross Motion For Summary Judgment

Because the Court, in this opinion, has dismissed Counts One, Two, Three, and Four of UMDNJ's complaint against HHS-IG, its cross-motion for summary judgment on those same counts is moot.

Appendix C

III. CONCLUSION

For the foregoing reasons, it is hereby ORDERED that Defendant's motion to dismiss is GRANTED, Defendant's motion for summary enforcement of subpoenas is GRANTED, and Plaintiffs' cross-motion for partial summary judgment is DENIED.

s/ Harold A. Ackerman
Hon. Harold A. Ackerman, U.S.D.J.
Jan 21st, 2003

APPENDIX D — ORDER ON REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT DATED DECEMBER 18, 2003

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 03-1268

THE UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY; THE COOPER HEALTH SYSTEM; UNIVERSITY PHYSICIAN ASSOCIATES OF NEW JERSEY, INC.

v.

DANA [sic] CORRIGAN, ACTING INSPECTOR GENERAL, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES*

The University of Medicine and Dentistry of New Jersey; The Cooper Health System; University Physician Associates of New Jersey, Inc.,

Appellants

*(Pursuant to Rule 43(c), F.R.A.P.)

(D.C. Civ. No. 99-cv-05046)

SUR PETITION FOR REHEARING

Appendix D

Present: SCIRICA, *Chief Judge*,
SLOVITER, NYGAARD, ALITO, ROTH, McKEE,
RENDELL, BARRY, AMBRO, FUENTES, SMITH
and WEIS*, *Circuit Judges*

The petition for rehearing filed by appellants, The University of Medicine and Dentistry of New Jersey and University Physician Associates of New Jersey, Inc., in the above-entitled case having been submitted to the judges who participated in the decision of this Court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular service not having voted for rehearing, the petition for rehearing by the panel and the Court en banc, is denied.

BY THE COURT,

/s/ Anthony J. Scirica
Chief Judge

Dated: December 18, 2003

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* As to panel rehearing only.

APPENDIX E — CONSTITUTIONAL PROVISIONS, TREATIES, STATUTES, ORDINANCES AND REGULATIONS

28 U.S.C. § 1331. Federal question

> The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.

28 U.S.C. § 1331.

The provisions of the Administrative Procedures Act ("APA"), 5 U.S.C. § 701, *et seq.*, relevant to this petition include:

§ 704. Actions reviewable

> Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.

5 U.S.C. § 704.

Appendix E

The provisions of the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, relevant to this petition include:

28 U.S.C. § 2201. Creation of remedy

(a) In a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under section 7428 of the Internal Revenue Code of 1986, a proceeding under section 505 or 1146 of title 11, or in any civil action involving an antidumping or countervailing duty proceeding regarding a class or kind of merchandise of a free trade area country (as defined in section 516A(f)(10) of the Tariff Act of 1930), as determined by the administering authority, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

(b) For limitations on actions brought with respect to drug patents see section 505 or 512 of the Federal Food, Drug, and Cosmetic Act.

28 U.S.C. § 2201.

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22 U.S.C. § 2202. Further relief

Further necessary or proper relief based on a declaratory judgment or decree may be granted, after reasonable notice and hearing, against any adverse party whose rights have been determined by such judgment.

22 U.S.C. § 2202.

The provisions of the Inspector General Act of 1978, as amended, 5 U.S.C.A. app. 3 §§ 1-12, relevant to this petition include:

§ 2. Purpose and establishment of Offices of Inspector General; departments and agencies involved

In order to create independent and objective units—

(1) to conduct and supervise audits and investigations relating to the programs and operations of the establishments listed in section 11(2);

(2) to provide leadership and coordination and recommend policies for activities designed (A) to promote economy, efficiency, and effectiveness in the administration of, and (B) to prevent and detect fraud and abuse in, such programs and operations; and

(3) to provide a means for keeping the head of the establishment and the Congress fully and currently informed about problems and deficiencies relating to the administration of such programs and operations and the necessity for and progress of corrective action.

5 U.S.C.A. app. 3 § 2.

§ 4. Duties and responsibilities; report of criminal violations to Attorney General

(a) It shall be the duty and responsibility of each Inspector General, with respect to the establishment within which his Office is established—

(1) to provide policy direction for and to conduct, supervise, and coordinate audits and investigations relating to the programs and operations of such establishment;

(2) to review existing and proposed legislation and regulations relating to programs and operations of such establishment and to make recommendations in the semiannual reports required by section 5(a) concerning the impact of such legislation or regulations on the economy and efficiency in the administration of programs and operations administered or financed by such establishment or the prevention and detection of fraud and abuse in such programs and operations;

(3) to recommend policies for, and to conduct, supervise, or coordinate other activities carried out or financed by such establishment for the purpose of promoting economy and efficiency in the administration of, or preventing and detecting fraud and abuse in, its programs and operations;

(4) to recommend policies for, and to conduct, supervise, or coordinate relationships between such establishment and other Federal agencies, State and local governmental agencies, and nongovernmental entities with respect to (A) all matters relating to the promotion of economy and efficiency in the administration of, or the prevention and detection of fraud and abuse in, programs and operations administered or financed by such establishment, or (B) the identification and prosecution of participants in such fraud or abuse; and

(5) to keep the head of such establishment and the Congress fully and currently informed, by means of the reports required by section 5 and otherwise, concerning fraud and other serious problems, abuses, and deficiencies relating to the administration of programs and operations administered or financed by such establishment, to recommend corrective action concerning such problems, abuses, and deficiencies, and to report on the progress made in implementing such corrective action.

5 U.S.C.A. app. 3 § 4.

Appendix E

§ 6. Authority of Inspector General; information and assistance from Federal agencies; unreasonable refusal; office space and equipment

(a) In addition to the authority otherwise provided by this Act, each Inspector General, in carrying out the provisions of this Act, is authorized—

(1) to have access to all records, reports, audits, reviews, documents, papers, recommendations, or other material available to the applicable establishment which relate to programs and operations with respect to which that Inspector General has responsibilities under this Act;

(2) to make such investigations and reports relating to the administration of the programs and operations of the applicable establishment as are, in the judgment of the Inspector General, necessary or desirable;

(3) to request such information or assistance as may be necessary for carrying out the duties and responsibilities provided by this Act from any Federal, State, or local governmental agency or unit thereof;

(4) to require by subpena [sic] the production of all information, documents, reports, answers, records, accounts, papers, and other data and

documentary evidence necessary in the performance of the functions assigned by this Act, which subpena [sic], in the case of contumacy or refusal to obey, shall be enforceable by order of any appropriate United States district court: *Provided*, That procedures other than subpoenas shall be used by the Inspector General to obtain documents and information from Federal agencies;

(5) to administer to or take from any person an oath, affirmation, or affidavit, whenever necessary in the performance of the functions assigned by this Act, which oath, affirmation, or affidavit when administered or taken by or before an employee of an Office of Inspector General designated by the Inspector General shall have the same force and effect as if administered or taken by or before an officer having a seal;

(6) to have direct and prompt access to the head of the establishment involved when necessary for any purpose pertaining to the performance of functions and responsibilities under this Act;

(7) to select, appoint, and employ such officers and employees as may be necessary for carrying out the functions, powers, and duties of the Office subject to the provisions of Title 5, United States Code, governing

appointments in the competitive service, and the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates;

(8) to obtain services as authorized by section 3109 of Title 5, United States Code, at daily rates not to exceed the equivalent rate prescribed for grade GS-18 of the General Schedule by section 5332 of Title 5, United States Code; and

(9) to the extent and in such amounts as may be provided in advance by appropriations Acts, to enter into contracts and other arrangements for audits, studies, analyses, and other services with public agencies and with private persons, and to make such payments as may be necessary to carry out the provisions of this Act.

5 U.S.C.A. app. 3 § 6.

§ 9. Transfer of functions

(a) There shall be transferred—

(2) to the Office of the Inspector General, such other offices or agencies, or functions, powers, or duties thereof, as the head of the establishment involved may determine are properly related to the functions of the Office and would, if so

transferred, further the purposes of this Act, except that there shall not be transferred to an Inspector General under paragraph (2) program operating responsibilities.

5 U.S.C.A. app. 3 § 9(a)(2).

§ 11. Definitions

As used in this Act—

(2) the term "establishment" means the Department of Agriculture, Commerce, Defense, Education, Energy, Health and Human Services, Housing and Urban Development, the Interior, Justice, Labor, State, Transportation, Homeland Security, or the Treasury; the Agency for International Development, the Community Development Financial Institutions Fund, the Environmental Protection Agency, the Federal Emergency Management Agency, the General Services Administration, the National Aeronautics and Space Administration, the Nuclear Regulatory Commission, the Office of Personnel Management, the Railroad Retirement Board, the Resolution Trust Corporation, the Federal Deposit Insurance Corporation, the Small Business Administration, the Corporation for National and Community Service, the Veterans' Administration, the Social Security Administration, the Tennessee Valley Authority, or the Export-Import Bank, as the case may be.

5 U.S.C.A. app. 3 § 11(2).

et seq., relevant to this petition include:

42 U.S.C.A. § 1395u. Use of carriers for administration of benefits:

(a) Authority of Secretary to enter into contracts with carriers

In order to provide for the administration of the benefits under this part [B] with maximum efficiency and convenience for individuals entitled to benefits under this part and for providers of services and other persons furnishing services to such individuals, and with a view to furthering coordination of the administration of the benefits under part A of this subchapter and under this part, the Secretary is authorized to enter into contracts with carriers, including carriers with which agreements under section 1395h of this title are in effect, which will perform some or all of the following functions (or, to the extent provided in such contracts, will secure performance thereof by other organizations); and, with respect to any of the following functions which involve payments for physicians' services on a reasonable charge basis, the Secretary shall to the extent possible enter into such contracts:

(1)(A) make determinations of the rates and amounts of payments required pursuant to this part to be made to providers of services and other persons on a reasonable cost or reasonable

part to be made to providers of services and other persons on a reasonable cost or reasonable charge basis (as may be applicable);

(B) receive, disburse, and account for funds in making such payments; and

(C) make such audits of the records of providers of services as may be necessary to assure that proper payments are made under this part.

42 U.S.C.A. § 1395u.

42 U.S.C.A. § 1395u(b)(7)(A)(i)(I) Applicability of competitive bidding provisions; findings as to financial responsibility, etc., of carrier; contractual duties imposed by contract:

(7)(A) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1395x(b)(6) of this title but which does not meet the conditions described in section 1395x(b)(7) of this title, the carrier shall not provide (except on the basis described in subparagraph (C)) for payment for such services under this part—

(i) unless—

> (I) the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought.

42 U.S.C.A. § 1395u(b)(7)(A)(i)(I).

The provisions of the Code of Federal Regulations relevant to this petition include:

> **42 C.F.R. § 405.521 (1992). Services of attending physicians supervising interns and residents**
>
> (a) Basic rules.
>
> (1) Attending physicians' services furnished to beneficiaries in a teaching setting are covered under Medicare Part B; and
>
> (2) The payment for these services is on the same fee schedule basis as other physician services except in those hospitals that have elected cost reimbursement under paragraph (d)(2) of this section.
>
> (b) Physician direction requirements. (1) Payment on the basis of the physician fee schedule applies to the professional services furnished to a beneficiary by the attending physician when the attending physician furnishes personal and identifiable

direction to interns or residents who are participating in the care of the patient.

(2) In the case of major surgical procedures and other complex and dangerous procedures or situations, the attending physician must personally supervise the residents and interns whom the physician involves in the care of the patients.

(3) Part B payment may be made for the services of an attending physician who involves residents and interns in the care of a patient only if the physician assumes and fulfills the same responsibilities for this patient as for other paying patients.

(4) The carrying out by the physician of these responsibilities is demonstrated by actions such as: Reviewing the patient's history and physical examination and personally examining the patient within a reasonable period after admission; confirming or revising diagnosis; determining the course of treatment to be followed; ensuring that any supervision needed by the interns and residents is furnished; and making reviews of the patient's progress.

Appendix E

42 C.F.R. § 415.172 (1996). Physician fee schedule payment for services of teaching physicians.

(a) General rule. If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought.

(1) In the case of surgical, high-risk, or other complex procedures, the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure.

(i) In the case of surgery, the teaching physician's presence is not required during opening and closing of the surgical field.

(ii) In the case of procedures performed through an endoscope, the teaching physician must be present during the entire viewing.

(2) In the case of evaluation and management services, the teaching physician must be present during the portion of the service that determines the level of service billed. (However, in the case of evaluation

and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of § 415.174 apply.)

APPENDIX F — INTERMEDIARY LETTER 372 DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE SUBJECT: PART B PAYMENTS FOR SERVICES OF SUPERVISING PHYSICIANS IN A TEACHING SETTING DATED APRIL 1969

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Social Security Administration
Baltimore, Maryland 21235

April 1969

BUREAU OF HEALTH INSURANCE
INTERMEDIARY LETTER NO. 372

SUBJECT: Part B payments for services of supervising physicians in a teaching setting

From questions which have been raised and from our onsite reviews, there appears to be a serious need to obtain a better and more uniform understanding among carriers, providers, and physicians of the conditions under which payment may be made under Part B for services rendered to patients by supervising physicians in the teaching setting and the method for determining the reasonable charge which may be recognized for such services. The enclosed guidelines are intended to clarify and supplement the criteria that govern reimbursement in this area as reflected in 886102.7, 6335, and 6720 ff. of the Part B Intermediary Manual.

Appendix F

Carriers are urged to review their present reimbursement practices in light of these guidelines and to take appropriate action as soon as possible to bring practices into conformity with the guidelines. The Part B Intermediary Manual will be revised to incorporate these clarifications and additions.

s/ Thomas Tichney
Thomas M. Tichney, Director
Bureau of Health Insurance

Enclosure

Appendix F

PART B PAYMENTS FOR SERVICES OF SUPERVISING PHYSICIANS IN A TEACHING SETTING

A. *Conditions Which Must Be Met for a Teaching Physician to be Eligible for Part B Reimbursement as an Attending Physician*

The physician* must be the patient's "attending physician." This means he must, as demonstrated by performance of the activities listed below, render sufficient personal and identifiable medical services to the Medicare beneficiary to exercise full, personal control over the management of the portion of the case for which a charge can be recognized; his services to the patient must be of the same character, in terms of the responsibilities to the patient that are assumed and fulfilled, as the services he renders to his other paying patients.

1. To be the "attending physician" for an entire period of hospital care, the teaching physician must as a minimum:

   a. review the patient's history, the record of examinations and tests in the institution, and make frequent reviews of the patient's progress; and

---

* The term "physician" does not include any resident or intern of the hospital regardless of any other tide by which he is designated or his position on the medical staff. For example, a senior resident who is referred to as an "assistant attending surgeon" or an "associate physician" would still be considered a resident since the senior year of the residency is essential to completion of the program.

b. personally examine the patient; and

c. confirm or revise the diagnosis and determine the course of treatment to be followed; and

d. either perform the physician's services required by the patient or supervise the treatment so as to assure that appropriate services are provided by interns, residents, or others and that the care meets a proper quality level; and

e. be present and ready to perform any service performed by an attending physician in a nonteaching setting when a major surgical procedure or a complex or dangerous medical procedure is performed; for the physician to be an "attending physician" his presence as an attending physician must be necessary (not superfluous as where, for example, the resident performing the procedure is fully qualified to do so) from the medical standpoint; and

f. be recognized by the patient as his personal physician and be personally responsible for the continuity of the patient's care, at least throughout the period of hospitalization.

EXAMPLE: A supervising physician carried out all of the activities listed above for a surgical patient but (e). He was not present in the OR when the major surgery was performed because

supervision of the 5th year resident performing the operation was not required. A physician's charge would not be recognized for the surgical procedure because criterion (e) was not met. Therefore, the physician would not be an attending physician for the period of hospital care although he might meet the criteria listed in A.2 below and be held as the attending physician for a portion of the care provided.

Even if the supervising physician chose to be present in the OR, payment could not be made to him for the surgical procedure since his presence was not medically necessary and he could not, therefore, function as the attending physician in connection with the surgery. However, if he was scrubbed and acted as an assistant, payment could be made to him as a surgical assistant if such an assistant was needed and another resident or physician did not fill the role (see item A.2 below).

If the supervising physician was present at surgery, and the surgery was performed by a resident acting under

his close supervision and instruction, he would not be the attending surgeon unless it were customary in the community for such services to be performed in a similar fashion to private patients who pay for services rendered by a private physician.

EXAMPLE: A group of physicians share the teaching and supervision of the house staff on a rotating basis. Each physician sees patients every third day as he makes rounds. No physician can be held to be one of these patient's attending physician for any portion of the hospital care although consultations and other services they personally perform for the patient might be covered.

2. A teaching physician may be held to be the attending physician for a portion of a patient's hospital stay: if the portion is a distinct segment of the patient's course of treatment (e.g., the pre-operative or post-operative period) and of sufficient duration to impose on the physician a substantial responsibility for the continuity of the patient's care; if the physician, as a minimum, performs all of the activities described above with respect to that portion of the stay; and if the physician is recognized as the patient's physician fully responsible for that part of the stay. If a teaching physician is not found to be the attending physician with respect to a

portion of a patient's stay, he may not be reimbursed for any service provided to the patient for that portion of the stay unless it is an identifiable service that he personally rendered to the patient.

EXAMPLE: A physician carried out all of the activities listed above for a surgical patient until midway in the post-operative period, when the physician's teaching tour of duty ended. Since he was not responsible for the continuing care of the patient throughout the post-operative period, he cannot be reimbursed as the attending physician for that period.

3. Performance of the activities referred to above must be demonstrated, in part, by notes and orders in the patient's records that are either written by or countersigned by the supervising physician.

4. The services of a teaching physician while visiting patients during grand rounds* is basically teaching and does not contribute to an "attending" relationship with any of the patients visited.

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* Editor's note: The term 'grand rounds' has come to refer to a teaching conference or lecture, which rarely occurs at the bedside. The term is apparently used here not in that sense, but to refer to bedside rounds for teaching purposes.

Appendix F

5. An emergency-room supervising physician may not customarily be considered to be the attending physician of patients cared for by the house staff. It is only through his direct personal involvement with a patient that a charge may be recognized under Part B. Such an involvement would necessarily include personal examination of the patient as well as direction of and responsibility for the treatment provided.

B. *Determining the Amount Payable Under Part B*

1. The amount paid for direct medical services rendered by the teaching physician should be related to only that discrete portion of the patient's care for which the physician exercised the pertinent responsibilities of an attending physician outlined in A.1. For example, if the patient's personal physician furnishes services before the hospital admission and after the discharge and the teaching physician becomes the attending physician only with respect to the inpatient care, the lesser extent of the teaching physician's service should be taken into account in recognizing a charge; otherwise the out-of-hospital service would be billed for and paid twice. Similarly, if surgery was performed and the teaching physician rendered identifiable personal service to the patient in the operating room, it is necessary to determine whether that physician performed services more nearly analogous to a consultant, an assistant at surgery (see first 'Example' in part A), or as the "attending"

surgeon in order to identify the appropriate reasonable charge. If the physician acted as the attending surgeon but did not render the pre- or post-surgical services generally performed by a private surgeon to a private patient, the difference in service should be reflected in the amount of reimbursement.

2. The following conditions should be taken into account in determining the "customary" charges of teaching physicians for services which they provide as attending physicians to Medicare beneficiaries.

   a. If the teaching physician has a substantial practice outside the teaching setting (i.e., more than half of the time spent in the practice of medicine is spent caring for people who were his patients before they were hospitalized or who were referred to him by physicians responsible for their care outside the hospital setting), his "customary" charges for services in the teaching setting will be related to the amounts he charges for similar services in his outside practice. Where the services performed in the teaching setting differ from those in the outside practice, reductions should be made for the lesser scope of services provided, time spent, visits or responsibility as an attending physician (not counting supervisory acts as time or visits).

   b. If the teaching physician does not have a substantial practice outside the teaching setting

and the provider has established one or more schedules of charges which are collected for medical and surgical services furnished to a majority of non-Medicare teaching patients, his charges should be related to the provider's schedule of charges which are most frequently collected.

EXAMPLE: A hospital with an approved teaching program receives payment for physicians' services rendered to 80 percent of its non-Medicare patients. Fifty percent are paid for by public assistance under a relatively low payment schedule; 20 percent are covered under a Blue Shield Plan with a somewhat higher fee schedule and the balances are covered under commercial plans. Since collections are made for a majority of patients and the most frequently used schedule of payment is the welfare schedule, the welfare schedule of charges should serve as the basis for determining the teaching physician's customary charges for Medicare.

c. Where neither the physician nor the provider has established charges for the physician's services which are in effect for non-Medicare patients, the carrier and intermediary must make the necessary charge and cost determination based on that

portion of the physician's compensation which is for services to patients, determined pursuant to the regulations governing reimbursement for the services of provider-based physicians.

3. Where teaching physicians of a hospital, billing through a hospital or other organization, adopt a uniform schedule of charges for the purpose of billing under Part B for the services they provide as attending physicians in the teaching setting, carrier acceptance of the schedule for reimbursement purposes should be based on a finding that the schedule does not exceed the average of reasonable charges which would be determined if each physician were individually reimbursed his reasonable charge for the services involved.

4. In determining the number of visits which may be considered reasonable, e.g., in a course of treatment for which a global fee is not ordinarily charged, the total number of visits which would have been made to the patient in a nonteaching setting should be used as a guide; visits in excess of this number are presumed to be primarily for teaching purposes. Similarly, total reasonable charges for a course of treatment in the teaching setting should be compared with and should not exceed the charges that would be expected in nonteaching settings for similar services. Also, the charges billed for an hour of a teaching physician's services should not exceed the amount of fees the physician generally receives for an hour's work in caring for nonteaching patients.

Appendix F

5. Where payment is made under Part B on a reasonable charge basis, payment may not also be made on a cost basis to the hospital for the same service as a teaching service. Part A payments to the hospital should therefore not be based on the total compensation of a physician if that compensation is in part for patient care. The total compensation should be reduced by the portion paid for patient care in accordance with the applicable provisions of the principles of reimbursement for services of hospital-based physicians to arrive at the hospital cost portion. Allocation of compensation received between both parts of the program should be in accordance with how the physician's time is actually spent. If a physician's only compensation for services in a teaching setting are paid by the hospital and the agreement states that only the supervisory, and not patient care, services are compensated, it is necessary to look behind the words of the agreement by reviewing the physician's actual obligations and activities and determining whether the compensation level is reasonable for the supervisory and teaching service alone and insufficient to cover patient care services as well. The carrier and intermediary should make this finding jointly.

   EXAMPLE: An employment agreement between a physician and the hospital states that he will be paid $50,000 a year for administration, supervision, and teaching. However, he spends one-half of his time in providing patient care. The carrier and intermediary determined

that if his compensation were allocated solely to the time the physician spent in the performance of his hospital duties, it would yield an hourly rate of compensation about double the rate paid for similar work elsewhere in the area. Therefore, the carrier and intermediary concluded that only a portion of the compensation was for hospital activities and reimbursable under Part A. Since charges were not customarily billed for the medical services the physician provided, the remainder would serve as a basis for computing the physician's reasonable charges for patient care in accordance with B.2.b above.

C. *Carrier Responsibility for Claims Review and Verification*

1. The carrier is responsible for assuring that the bills being submitted were prepared with an understanding of the conditions governing payment for physicians' services in the teaching setting.

   To help carry out this responsibility, carriers will not pay bills (SSA-1490 or SSA-1554) for services rendered in the teaching setting in any month after May 1969, unless:

   a. the chief of the department or service involved certifies on a form furnished by the carrier that each of the billed services for that month meets the pertinent requirements of A.1 and A.2; or

b. the bill has been signed by the attending physician and he understands that he is certifying that he met the requirements for those services for which the claim is made.

2. The provision of personal and identifiable services must be substantiated by appropriate and adequate recordings entered personally by the physician in the hospital or, in the case of outpatient services, outpatient clinic chart. The carrier is expected as part of its responsibilities to make appropriate checks of patient records, examining admission, progress, and discharge notes to verify that services for which charges are billed met the appropriate coverage criteria. If the carrier review shows that a significant portion of the services in the sample do not meet the criteria, appropriate steps should be taken to adjust the reimbursement.

3. Bills must indicate when services are furnished in the teaching setting, the name of the provider and attending physician involved, and the extent of the services provided as an attending physician. The services must be defined and quantified to avoid errors in applying the reasonable charge limitation—e.g., to avoid applying the reasonable charge for a global service where only the surgical procedure or another component service was provided as an attending physician.

4. The carrier will need to carry out the steps necessary to assure itself that these conditions set out in B.1 are met—for example, to assure itself that any schedule of charges proposed for the teaching setting is actually applied and collected.

D. *Who May Bill*

Where the supervising physician is a member of a group which provides teaching services in a hospital, the Part B payment for services rendered as attending physicians by the group may be billed for:

1. by the physician or a corporation, partnership, or other organization of physicians (including an association of teaching physicians organized for the purpose of billing for and distributing insurance monies and other payments received for professional services to patients) on form 1490;

2. by the hospital on form 1554 provided that the carrier has determined that the certification described in C.1.A has been executed and complied with; and

3. if the services are performed by a physician who is a faculty member of a medical, osteopathic, or dental school, by the school on form 1490.

The individual physician's authorization is required to be on file in writing with the hospital or other organization to permit any of the above organizations to

bill on his behalf. The organization must furnish to the Part B carrier the names of the physicians who have authorized the organization to bill on their behalf, and must agree to keep the carrier informed on a current basis of changes in membership in the group.

APPENDIX G — LETTER FROM THOMAS A. AULT DATED APRIL 27, 1995

Mr. Robert J. Saner
Washington Counsel, MGMA
Powers, Pyles, Sutter & Verville, P.C.
Attorneys At Law
Third Floor
1275 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2404

Dear Mr. Saner:

I am responding to your letter regarding implementation of a "physician presence" requirement for attending physicians' services by the Part B carrier for South Carolina.

It is our position that carriers which did not apply a "physician presence" requirement prior to the issuance of the Charles R. Booth memorandum of December 30, 1992, should not institute such a policy until a revised rule on payments for teaching physicians' services is finalized. In that regard, you have received a letter from the carrier medical director for South Carolina explaining the basis for the misunderstanding and clarifying that the carrier would not be changing its policy pending revised national guidelines.

I hope that this matter is now resolved.

Sincerely,
s/ Thomas A. Ault
Director
Bureau of Policy Development

APPENDIX H — LETTER FROM JUNE GIBBS BROWN, INSPECTOR GENERAL DATED JUNE 21, 1996

Jordan J. Cohen, M.D.
President
Association of American Medical Colleges
2450 N Street, N.W.
Washington, D.C. 20037

Dear Dr. Cohen:

The purpose of this letter is to apprise you of activities in my office that may be of interest and concern to members of your organization. Specifically, the Department of Health and Human Services, Office of Inspector General (OIG), has initiated a series of nationwide reviews of compliance with rules governing physicians at teaching hospitals (PATH) and other Medicare payment rules. This initiative grows out of the extensive work performed by the OIG at a major east coast university. The focus of the review was compliance with Intermediary Letter 372 (IL 372), the Medicare rule affecting payment for physician services provided by residents. We found that the institution was not complying with this rule. We also found that teaching physicians were improperly "upcoding" the level of service provided in order to maximize Medicare reimbursement. This review resulted in the Government's recovery of more than $30 million, including damages under the Federal Civil False Claims Act. As part of the negotiated settlement, the responsible parties also avoided program exclusion under the OIG's authorities.

Appendix H

The OIG has initiated the PATH project in order to determine whether, and to what extent, similar problems are present at other teaching institutions throughout the country. The nationwide PATH reviews will focus on compliance with IL 372 and the appropriateness of service codes. In addition, the OIG encourages physician group practices affiliated with teaching hospitals to examine their own practices under these Medicare requirements. Interested group practices that choose to participate actively in such a process, under a protocol established by the OIG, may potentially reduce their legal exposure, if any, under the OIG's exclusion authorities.

Active participation includes arrangement, at the party's expense, for an independent review conducted by a third party, using the OIG's review protocol. A prospective party must be an institution that receives graduate medical education payments under Medicare Part A. To receive the benefits of active participation in a PATH review, a party must adhere to principles set out in the review protocol, such as the following:

- The party will not engage, for the purposes of the independent review, any individual or entity that has previously provided advice or consultation to the party with respect to the matter under review.

- The party will waive any privileges or other rights to withhold any documents, as requested by the Government and relating to the review, including documents otherwise protected by the attorney-client privilege and the work product doctrine.

- The Government will receive all draft reports of the independent review concurrently with the party, and the party will afford the Government the opportunity to be present for any discussions with the reviewer relating to the review.

- The party understands that the Government reserves the right to conduct its own review, of any scope, during the pendency of the review process, and to refer matters when appropriate to other Federal authorities such as the Department of Justice.

The OIG will give favorable treatment, to the degree permitted by law, to the party's bona fide participation and cooperation under the protocol. Favorable treatment may include:

- generally crediting the independent reviewer's reasonable and verifiable damages estimate for the purposes of determining overpayment;

- according substantial weight to the level of participation and cooperation in determining whether to exclude the party under the OIG's exclusion authorities; and

- making the party's level of participation and cooperation known to other Federal officials in the event that the OIG's statutory obligations require referral of the matter under review.

Appendix H

We are writing to inform you about our activities under PATH because some of your members may be interested in participating and working with us to resolve any issues that may arise under a PATH review.

The OIG is committed to working with responsible parties to resolve their liabilities relating to the matters under review, if any, and to assure future compliance with Medicare laws, regulations and payment rules. Parties interested in actively participating in the PATH reviews should contact:

Ms. Eileen Bechkes, Audit Manager
Department of Health and Human Services
Office of Inspector General
Office of Audit Services
N2-25-26
7500 Security Boulevard
Baltimore, Maryland 21244-1850
(410) 786-7104

Thank you for you assistance in notifying your members of our work in this area.

Sincerely,
s/ June Gibbs Brown
June Gibbs Brown
Inspector General

APPENDIX I — LETTER FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES DATED JULY 11, 1997

Jordan J. Cohen, M.D.
President
Association of American Medical Colleges
2450 N Street, N.W.
Washington, D.C. 20037-1127

P. John Seward, M.D.
Executive Vice President
The American Medical Association
515 North State Street
Chicago, Illinois 60610

Dear Drs. Cohen and Seward:

The Secretary directed me to explore the concerns raised by the Association of American Medical Colleges, the American Medical Association and others regarding the Office of Inspector General's (OTG's) Physicians at Teaching Hospitals (PATH) initiative. Doing a thorough review has taken more time than I would have hoped. However, I am now able to offer a considered and informed judgment on this matter.

At the outset, I would like to thank you for the information and materials your organizations provided to me and my colleagues regarding PATH. Your efforts were quite helpful in broadening our understanding of this matter. In addition, we reviewed our own documentary history and engaged in extensive discussions with senior officials in the Health Care Financing Administration (HCFA) and OIG. I appreciate that

the Inspector General and her colleagues undertook considerable work with my office to explain their practice and perspective on this matter.

In view of the level of interest in and concern over this matter, it may be useful for me to lay out my thinking on the legal basis for audits of teaching physician claims under PATH. One factor critical to my thinking has been the need to distinguish Part B from Part A reimbursement for physicians in hospitals.[1] As you know, supervision of interns and residents by teaching physicians is reimbursed under Medicare Part A through graduate medical education (GME) payments. By this mechanism, teaching physicians are paid for taking responsibility for the hospital's oversight of its doctors in training. It would be absurd to assert that physicians could receive the significant remuneraton that characterizes Part B reimbursement for supplying the same level of services that qualifies and was paid for as Part A services. The physical presence of a physician with the treating intern or resident at the time of treatment is one clear indication of a more patient-specific level of responsibility for the physician entitling her or him to Part B, rather than Part A, reimbursement. That view is consistent with both common sense and the history of this subject as recounted below.

Over the past months, my colleagues and I have reviewed hundreds and hundreds of pages of documents related to the issue of physician presence as an element of Part B reimbursement. Over decades, there have been numerous

1. *See, e.g.*, 42 U.S.C. § 1395xx(a)(1). [Copies of this and other materials referenced herein are attached to this letter.]

policy insurances describing the circumstances in which Medicare Part B payments would be made to teaching physicians. The sample that follows offers a sense of their pattern and content.

HCFA's statements on this subject are contained in various forms and appear in diverse iterations. The standard for making Part B teaching physician payments is variously expressed as requiring "personal and identifiable direction" to interns or residents or, in the case of major surgical procedures or other complex and dangerous situations, as requiring "personal and identifiable direction . . . includ[ing] supervision in person."[2] Elsewhere, the touchstone is "either perform[ing] the physician's services . . . or supervis[ing] the treatment . . . by interns, residents or others . . ." or, in the case of major, complex or dangerous situations, "be[ing] present and ready to perform any services."[3]

A central office memorandum[4] sent to all Part B carriers instructed that services would be covered where the record shows "the presence of the physician, with sufficient frequency, on occasions of services rendered. . . .[5] Another

2. 20 C.F.R. § 405.521 (1967).

3. Intermediary Letter (IL) 372. sections A.1.d and A.1.e., April 1969.

4. The memorandum was sent by the Bureau of Health Insurance of the Social Security Administration, the predecessor agency to HCFA.

5. Memorandum to All Part B Carriers from Bureau of Health Insurance, September 3, 1969.

central office memorandum states that attending physicians may bill for Part B services "where entries in the medical record indicate that the physician was, at a minimum, present when the service was rendered."[6]

In 1976, the Medicare Carriers Manual was amplified by instructions that Part B payment was to be made when the physician provided "personal and identifiable direction to interns or residents. . . ." For major surgical procedures and other complex and dangerous procedures or situations, "such personal direction must include supervision in person. . . ."[7]

A 1980 statutory amendment provided that teaching physician services would be payable under Part B only if "the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management portion of the case for which the payment is sought. . . ."[8]

In 1995, HCFA recognized that its issuances were "vague, perhaps necessarily, on the matter of the presence of the physician. . . ."[9] This acknowledgment by the agency was

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6. Memorandum from Deputy Director, Program Policy, BHI to Regional Representative, HI, Boston, August 21, 1972.

7. Medicare Carriers Manual § 8201.

8. 42 U.S.C. § 1395u(b) (7) (A) (i) (T). *See also* 42 C.F.R. § 405.521 (1991), 48 Fed. Reg. at 53,507 (1991), and Medicare Carriers Manual § 15106.

9. 60 Fed. Reg. at 63,138 (1995).

consistent with one that appeared in a proposed but not finalized rule published in 1989, where HCFA recognized the wide differences among teaching hospitals in the levels of physician involvement as well as a need for HCFA to specify the level of involvement necessary to justify Part B payment to teaching physicians.[10] Much of the complication may have been attributable to the twin concerns of physician presence and meeting the attending physician standard. In order to reduce the complexity of making those determinations, HCFA said in the preamble to its 1995 regulation: "We believe that the most important consideration should be the presence of the teaching physician during the key portion of the service . . . and that requiring both an attending physician relationship and the presence of that same physician during every billable service is no longer warranted."[11] Consequently, HCFA dropped the attending physician standard and focused exclusively on physician presence as the touchstone for Part B billing.[12]

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10. 54 Fed. Reg. at 5948 (1989).

11. 60 Fed. Reg. at 63,139 (1995).

12. The concept of the attending physician had been introduced through Intermediary Letter 372 in April 1969. The notion contemplated that only one doctor at a time could be the attending physician and that only the attending physician could bill under Part B for services performed by an intern or resident. *See, e.g.*, Part A Intermediary Letter No. 70-7 and Part B Intermediary Letter No. 70-2. "Questions and answers relating to implementation of Intermediary Letter No. 372." January 1970, Questions 5 and 12. HCFA guidance assumed that successive doctors could be the attending physicians, each for a portion of the hospital stay, but

(Cont'd)

As this recitation of official policy in a scattering of issuances makes evident, the standards for paying teaching physicians under Part B of Medicare have not been consistently and clearly articulated by HCFA over a period of decades. When HCFA policy is not unambiguously clear, carrier clarification is warranted and appropriate. Thus, where a carrier informed a teaching institution that physicians must either personally furnish a service or be present when it is furnished by an intern or resident in order to be reimbursed under Part B, that guidance would be controlling.

And, indeed, carriers across the country, did provide very clear guidance on this subject over years to teaching physicians and institutions. Again, out of hundreds of pages of documentation, a sample of such guidance reflects that fact. One carrier issued instructions that Part B payment is contingent on satisfying the "attending physician criteria and the physician's presence at the time the service was provided by the house staff."[13] Another carrier instructed that documentation supporting Part B bills must show whether

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(Cont'd)
tracking who was the attending at any given moment became excessively costly and administratively cumbersome. Because there was no reason to do that tracking to determine which of a team of doctors caring for a patient was the attending — so long as each doctor on the team provided more than Part A services — HCFA allowed the attending physician rule to slip into desuetude. The formal abandonment of the rule in 1995 followed decades of disuse.

13. Medicare B-Teaching Physicians Manual prepared by Wisconsin Physician Services in conjunction with HCFA at 4 (1983).

"each service billed . . . [was] actually rendered by the physician or rendered in his presence."[14]

Another instructed that attending physicians "must be personally present at the time of the service" in order to bill for Part B compensation.[15] In describing the documentation necessary to support a Part B bill, another carrier stated that "[w]e cannot accept notes written by the resident when there is no indication of the teaching physician's presence . . ." since "[t]his type of documentation does not clearly show the physician's presence, much less his participation in the patient's care."[16]

The foregoing established the frame of reference for conversations with the OIG in which that Office informed me that PATH I and II audits will be conducted pursuant to the following guidelines.[17]

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14. Manual for Teaching Physicians prepared by Equicor Medicare Administration at 3 (1991).

15. Letter from The Travelers to the University of Virginia, April 17, 1992.

16. Letter from Transamerica Occidental Life Insurance Company to Family Practice Center, September 16, 1985.

17. The Department of Justice is engaged, under its own authorities, in cases concerning Part B billing by physicians in teaching hospitals. Nothing in this letter purports to or could constrain actions of the Department of Justice in pursuit of its own matters. The OIG may be requested to assist the Department of Justice in some of these matters. The OIG's responses to such requests will be grounded in the commitments made by the OIG and reflected in this letter.

before December 30, 1992, issued clear explanations of the rules regarding reimbursement for the services of teaching physicians.[18] Thus, claims for services of teaching physicians will be considered for a PATH I or II audit only where a carrier provided written guidance stating that Part B reimbursement for teaching physician services would be limited to one of two situations: when the teaching physicians either personally furnished services to Medicare beneficiaries or were physicially present when the services were furnished by interns or residents.

Second, OIG will not approach a hospital to open PATH discussions unless and until OIG has obtained carrier materials showing that clear instructions on the need for teaching physicians to be physically present were given to the institutions or physicians served by that carrier.

Third, a hospital approached by OIG will have the opportunity to show, as a matter of fact, that it or the teaching physicians at the institution received guidance from the carrier which the hospital views as contradictory to the standard referenced above. Until that opportunity has been provided and any submission reviewed, no additional information will be requested by OIG from the hospital nor will a PATH audit be conducted.

The decision whether clear guidance was given by carriers to teaching hospitals and physicians will be made by OIG. That determination is, necessarily, a fact bound one and will have to be made particularly and in each instance.

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18. A flurry of HCFA statements, starting with one on December 30, 1992, and continuing prior to implementation of the new physician presence standard on July 1, 1996, unnecessarily unsettled matters.

That determination is, necessarily, a fact bound one and will have to be made particularly and in each instance.

Fourth, I want to address the issue of auditing for upcoding of services. When HCFA adopted new evaluation and management codes in 1992, the agency began a collaborative process with institutions and physicians to train persons who would be using the codes and to review the experience under the new regime. In so doing, HCFA made a commitment not to audit claims using the new codes until August 1995. At the same time, HCFA instructed its Regional Administrators that, during the period of training prior to August 1995, action could be taken at any time to deal with egregious cases of abuse or fraud.[19] Thus, where OIG finds egregious cases of upcoding abuse or fraud as it audits pre-August 1995 records, such matters are appropriate for attention and resolution.

Fifth, in an exercise of enforcement discretion, if OIG determines not to engage in a PATH I or II audit on the physical presence requirement, OIG will not pursue a PATH audit for upcoding of physician services. The decision not to pursue a PATH upcoding audit will not preclude a non-PATH based upcoding audit of services at a teaching hospital. Occasions for an upcoding audit might include receipt of information from a whistleblower or the filing of a *qui tam* complaint. In those and other circumstances, OIG places no limit on its intention to pursue such an audit.

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19. *See, e.g.*, Memorandum of October 4, 1994 from Director, Office of Medicare Benefits Administration, HPO to All Associate Regional Administrators for Medicare.

Appendix I

Finally, in a related matter, during any continuing or new PATH I or II audits, OIG will continue to credit a hospital's submitted undercoded claims against upcoded claims, thereby reducing the amount of any Medicare overpayment.

It has taken time to bring this matter to this point because of the importance we place on ensuring consideration of the positions of all concerned. I hope that you find the principles outlined above a fair and clear statement regarding the PATH initiative. Thank you for your assistance and cooperation.

Sincerely,

s/ Harriet S. Rabb
Harriet S. Rabb

APPENDIX J — AUDIT STANDARDS FOR AUDIT OF PHYSICIANS AT TEACHING HOSPITALS OF COOPER HEALTH SYSTEM

AUDIT STANDARDS FOR AUDIT OF PHYSICIANS AT TEACHING HOSPITALS AT COOPER HEALTH SYSTEM

As co-client, the Department of Health and Human Services, Office of the Inspector General, Office of Audit Services (OIG) sets out the following standards to be used in the audit of Medicare claims as a part of the Physicians at Teaching Hospitals (PATH) initiative. These are the general standards to be followed in evaluating the medical records. Any questions about interpretations or details should be addressed to Thomas Grippe (212-264-4044) or Kenneth Heffner at (609-989-2073).

Physician Services/Presence Issue

Medicare Part B reimbursement for teaching physician services is limited to one of two situations: (1) when the teaching physician either personally furnished service(s) to the Medicare beneficiary; or (2) when the billing physician was functioning as the attending physician and was present when the service(s) was furnished by the intern or resident. The presence of the physician must be documented in the medical record by either recording(s) personally entered by the billing physician, or recordings written by the intern or resident which discuss the physician's presence. (Other sources of information (*e.g.*, nursing notes or operating room logs) could also be used to demonstrate the physician's presence.) The billing physician's countersignature on notes or reports by a

resident, intern or nurse will not be accepted unless the notes, reports or other evidence in the patient's hospital records confirm that the physician was present when the services were rendered.

Evaluation & Management Codes

The Evaluation and Management Codes are to be evaluated using the 1995 or 1996 American Medical Association Physician's Current Procedural Terminology (CPT) standards for determining level of coding. The claims should be evaluated to determine if the level of service billed is justified based on the documentation contained in the medical records. If not, determine if there is an over- or under-code.

Other Coding

Using the same CPT, evaluate all services for correct coding, including correct use of Modifiers.

Other

The Reviewers should consider any other situations which they may observe in the medical records and any effect those errors may have on Medicare reimbursement.

Supreme Court, U.S.
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(3)

No. 03-1339

In the Supreme Court of the United States

UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY, ET AL., PETITIONERS

v.

DARA CORRIGAN, ACTING INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the Inspector General Act prohibits the Inspector General of the Department of Health and Human Services from conducting an audit or investigation of potential fraud or abuse by a Medicare provider absent a referral from the providers' Medicare carrier or other particularized evidence of fraud.

2. Whether the Inspector General's decision to undertake an investigation of potential fraud or abuse by recipients of Medicare funds is final agency action subject to judicial review prior to any enforcement action.

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BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-32a) is reported at 347 F.3d 57. The opinion of the district court (Pet. App. 35a-69a) is not reported.

JURISDICTION

The judgment of the court of appeals was entered on October 17, 2003. A petition for rehearing was denied on December 18, 2003 (Pet. App. 70a-71a). A petition for a writ of certiorari was filed on March 16, 2004. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. Title XVIII of the Social Security Act (Medicare Act), 42 U.S.C. 1395 *et seq.*, establishes a federally subsidized health insurance program primarily for persons over age 65. The program is administered by the Centers for Medicare and Medicaid Services (CMS), previously known as the Health Care Financing Administration (HCFA), within the Department of Health and Human Services (HHS). CMS, in turn, contracts with insurance companies throughout the nation, called carriers, which are responsible for communicating Medicare policy in the locale they serve, processing and paying claims, and conducting post-payment audits. The Medicare program has two principal parts. This case relates to circumstances in which these two parts overlap, presenting a risk that Medicare providers will bill the program twice for the same services.

Part A of Medicare, 42 U.S.C. 1395c-1395i, provides insurance for the costs of institutional care. Part A payments contribute to the costs of training residents and interns, including their salaries and the salaries of teaching physicians. 42 U.S.C. 1395ww(d) and (h). In 1996, Medicare Part A paid over $8 billion to teaching hospitals for the costs of training their residents and interns, or approximately $100,000 per resident or intern. C.A. App. A309.

Part B of Medicare, 42 U.S.C. 1395j-1395w, provides insurance to reimburse for specific medical services provided to a patient. Because Medicare already contributes to teaching supervision through Part A, teaching physicians may not seek reimbursement under Part B for merely providing general supervision to residents. Rather, in order to receive compensation under

Part B, a teaching physician must "render[] sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought." 42 U.S.C. 1395u(b)(7)(A)(i)(I).

During the time period covered by the audits here at issue, the Secretary's regulations authorized payment under Medicare Part B only where the teaching physician both was the "attending physician" and "furnishe[d] personal and identifiable direction to interns or residents who [we]re participating in the care of the patient." 42 C.F.R. 405.521(b)(1) (1993). The Secretary interpreted that regulation, together with a general requirement that Medicare will pay only where "[t]he services are personally furnished for an individual patient by a physician," 42 C.F.R. 405.550(b)(1), to require that the teaching physician must at least be physically present at the time the services were performed in order to be eligible for payment under Part B. See, *e.g.*, Centers for Medicare & Medicaid Services, HHS, *Carriers Manual* § 8201(A) (visited May 19, 2004) <http://www.cms.hhs.gov/manuals/14_car/3b8201.asp> (if teaching physician did not personally perform the service, medical record should indicate that the "physician was physically present when the service" was rendered).[1]

b. Congress enacted the Inspector General Act (the IG Act), 5 U.S.C. App. 1 *et seq.*, at 12, in 1978 in order to

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[1] The Secretary revised the regulations effective July 1, 1996. The current regulation eliminates the "attending physician" requirement, but carries forward and makes explicit in the text of the regulations themselves the requirement that "services * * * furnished by a resident [must be performed] in the presence of a teaching physician." 42 C.F.R. 415.170 (2002).

curb "fraud, abuse and waste in the operations of Federal departments and agencies and in federally-funded programs." S. Rep. No. 1071, 95th Cong., 2d Sess. 4 (1978). The IG Act created an Office of Inspector General (OIG) for numerous agencies, into which Congress consolidated various audit and investigation responsibilities, see 5 U.S.C. App. 2(1), 3(a), 9(a), at 12, 13, 32. In the case of HHS (then the Department of Health, Education, and Welfare), Congress had previously created an Inspector General (IG), with responsibilities and powers similar to those conferred by the IG Act. Act of Oct. 15, 1976, Pub. L. No. 94-505, Tit. II, 90 Stat. 2429. The IG Act, as amended by Pub. L. 100-504, transferred that pre-existing office to a new HHS OIG. 5 U.S.C. App. 9(a)(1)(F), at 32.

Sections 4 and 6 of the IG Act vest the IG with broad authority to "conduct, supervise, and coordinate audits and investigations relating to [HHS] programs," such as Medicare, 5 U.S.C. App. 4(a)(1), at 15, as well as to conduct activities designed to "promot[e] economy and efficiency" and "prevent[] and detect[] fraud and abuse" in the agency's "programs and operations," 5 U.S.C. App. 4(a)(3), at 15. See also 5 U.S.C. App. 2(1) and (2), at 12 (same). The IG enjoys broad discretion "to make such investigations * * * relating to the administration of the programs and operations of [HHS] as are, in the judgment of the Inspector General, necessary or desirable." 5 U.S.C. 6(a)(2), at 19.

c. In 1996, an audit by the HHS OIG of the University of Pennsylvania Health System revealed a dramatic lack of documentation that teaching physicians were physically present during services for which Medicare had been billed and, further, that Medicare was being billed for a more complex level of care than was actually provided. The University of Pennsylvania

audit resulted in a $30 million settlement. Pet. App. 7a. In light of that audit, the HHS OIG developed the Physician at Teaching Hospital (PATH) initiative to focus on the two forms of potential over-billing discovered at the University of Pennsylvania. *Id.* at 8a. PATH audits are conducted by HHS-OIG at its own cost. Alternatively, if a provider so chooses and OIG agrees, the provider may hire an independent reviewer to conduct a "self-audit" and report the findings to the HHS OIG. *Ibid.*

In 1996, the HHS OIG informed petitioners and other teaching hospitals of its intent to conduct a PATH audit of their Medicare reimbursements. After certain providers objected that the Secretary and his carriers had not sufficiently made clear the "physical presence" requirement for teaching physicians, the HHS OIG conducted a broad review of the guidance that the agency and carriers had provided on the subject. Pet. App. 7a-8a. The HHS OIG found that the Secretary and the "overwhelming majority" of regional carriers had "consistently * * * read [the regulatory language] to require the attending physician's physical presence when a resident performed a service," in order to qualify for Part B reimbursement. C.A. App. A322. The HHS OIG acknowledged, however, that "some carriers did not enforce a 'physical presence' standard." *Ibid.* The HHS OIG therefore announced that it would undertake PATH audits "only where carriers * * * issued clear explanation[s] of the rules regarding reimbursement for the services of teaching physicians." *Id.* at A323.

In response to the teaching hospitals' objections, HHS's General Counsel, Harriet Rabb, also reviewed the issue of Part B payments to teaching physicians. On the same day that the HHS OIG issued its PATH

Overview, the General Counsel sent a letter to the Association of American Medical Colleges and the American Medical Association (the Rabb Letter), responding to their concerns. The letter endorsed the approach adopted by the HHS OIG—to investigate those providers whose carriers had provided clear instruction of the physical presence requirement. Pet. App. 9a.

The Rabb Letter first observed that no physician could reasonably have believed he could be compensated under Medicare Part B for a merely supervisory role. "It would be absurd to assert that physicians could receive the significant remuneration that characterizes Part B reimbursement for supplying the same level of services that qualifies and was paid for as Part A services." Pet. App. 109a. The Rabb Letter noted several HCFA publications that had specifically referred to the physical presence requirement, but recognized that the standard had been stated in various ways. *Id.* at 110a-112a. In the General Counsel's view, because HCFA's own guidance was "not unambiguously clear," providers would have had to look to the carriers for clarification, and "that guidance would be controlling." *Id.* at 113a. "[I]ndeed," the General Counsel observed, "carriers across the country did provide very clear guidance on this subject," and she quoted several that stated the "physician's presence" requirement quite explicitly. *Ibid.* The Rabb Letter further stated the General Counsel's agreement with the HHS OIG's decision only to undertake PATH audits where the carrier had adopted a clear position that the treating physician's physical presence was required. *Id.* at 115a.

The HHS OIG has informed this Office that, pursuant to the PATH initiative, it has undertaken audits of 32

teaching hospitals. Of those audits, 29 have been completed. The HHS OIG has also informed this Office that PATH audits have recovered nearly $130 million for the Medicare program, in addition to another roughly $100 million recovered in non-PATH audits that encompassed PATH-related issues.

d. In 1997, the HHS OIG reviewed the written policies of petitioners' Medicare carrier and determined that they showed a clear policy of requiring a teaching physician's physical presence as a condition for reimbursement under Medicare Part B. See, *e.g.*, C.A. App. A285 ("The supervising physician * * * *should personally provide* all services reported for Medicare Part B payment or *be present* when the resident renders the services.") (emphases added). The HHS OIG also determined that petitioners had adequate notice of the carrier's interpretation through manuals that directed the providers to the appropriate publication for guidance concerning Part B payments to teaching physicians. *Ibid.*

Petitioners initially agreed to cooperate with the PATH audits and voluntarily elected to employ an independent auditor, rather than having the HHS OIG conduct the audit directly. Instead of going forward with the audits, however, petitioners filed this action, challenging the audits. The HHS OIG subsequently issued administrative subpoenas to petitioners to produce the necessary documents, and counter-claimed to enforce the subpoenas. Pet. App. 11a.

2. The district court dismissed petitioners' suit and granted the government's motion for enforcement of the subpoenas. Pet. App. 39a-69a. The district held that petitioners' challenge to the HHS OIG's audit failed to satisfy at least three separate requirements for review under the Administrative Procedure Act (APA),

5 U.S.C. 551 *et seq.* First, the IG's decision to initiate an audit was neither "final agency action" nor ripe for review, because it was merely the beginning of an investigation without immediate impact on petitioners' day-to-day operations. Pet. App. 52a-53a, 56a-57a. Further, petitioners had an adequate alternative remedy because any challenge to the IG's interpretation of the Medicare regulations could be raised in defense against any enforcement action, if one were ever brought. *Id.* at 54a-55a. Finally, the IG Act committed the decision whether to perform an audit to the HHS OIG's sole discretion. *Id.* at 55a-56a. In granting the government's motion to enforce the administrative subpoenas, the court found that the investigation was within the authority conferred on the IG by Section 6(a)(2) of the IG Act. *Id.* at 56a, 64a-68a.

3. The court of appeals affirmed. Pet. App. 1a-32a. The court held, as petitioners conceded, that the HHS OIG's statutory charge "to prevent and detect fraud and abuse" in the Medicare program encompassed the authority to audit not only the agency's own operations, but also to audit directly the recipients of Medicare funds. *Id.* at 17a. The court rejected petitioners' attempt to circumscribe that authority to instances where "the inspector general has received a referral from a carrier, or is otherwise responding to a specific allegation of fraud." *Ibid.* The court held that "[t]he inspector general's mandate to prevent and detect fraud and abuse is not limited by HHS's—or its agents' —own efforts to prevent and detect fraud and abuse." *Id.* at 19a.

The court further held that it lacked jurisdiction over petitioners' challenge to the standard that the IG intended to use in her audit. Two members of the panel held, following *FTC* v. *Standard Oil Co.*, 449 U.S. 232

(1980), that the IG's decision to conduct an investigation and to utilize a particular standard in her audit was not sufficiently ripe or final for judicial review. The court recognized that the decision to initiate an investigation is "a *preliminary* step—non-final by definition—leading toward the possibility of a 'final action' in the form of an enforcement" that may never materialize. Pet. App. 24a. In response to petitioners' reliance on the immediate need to comply with the IG's audit requests, the court observed that "[a]lthough this burden certainly is substantial, it is different in kind and legal effect from the burdens attending what heretofore has been considered to be a final action." *Id.* at 28a (quoting *Standard Oil*, 449 U.S. at 242).

Judge Ambro concurred. Pet. App. 31a-32a. He declined to join the majority's analysis concerning finality but viewed the IG's decision to undertake an audit as unreviewable because it was "committed to agency discretion," 5 U.S.C. 701(a)(2), by Section 6(a)(2) of the IG Act, which authorizes the IG "to make such investigations * * * relating to the administration of the programs and operations of [HHS] as are, in the judgment of the [IG] necessary or desirable." Pet. App. 32a.

ARGUMENT

The decision of the court of appeals is correct and does not conflict with any decision of this Court or any other court of appeals. Accordingly, the petition for a writ of certiorari should be denied.

1. a. Petitioners argue that the HHS OIG may audit Medicare providers only when there has been a fraud referral from a carrier. Pet. 11-24. That contention lacks merit. The IG Act provides that the inspector general is "to provide leadership * * * for activities designed * * * to promote economy, efficiency, and

effectiveness * * * and * * * to prevent and detect fraud and abuse" in her agency's programs. 5 U.S.C. App. 2(2), at 12. See also 5 U.S.C. App. 4(a)(3), at 15 ("It shall be the duty and responsibility of each Inspector General * * * to conduct, supervise, or coordinate * * * for the purpose of promoting economy and efficiency in the administration of, or preventing and detecting fraud and abuse in [the agency's] programs."). The IG Act thus assigns to the inspectors general an active and *leading* role in combating fraud, waste and abuse, and, more generally, in promoting economy and efficiency in their respective agency's programs. In fulfilling that mission, an inspector general must exercise independent initiative to investigate possible fraud and abuse, rather than wait for other offices or individuals to bring such accusations to her. The statute's use of the verbs "prevent" and "detect" also necessarily signify authority to investigate potential fraud or abuse even when the IG has no specific evidence that fraud or abuse has occurred. The court of appeals correctly held that Congress did not restrict the IG to acting only when another office or individual had discovered evidence of fraud.

Petitioners also argue (Pet. 11-24) that the HHS OIG's PATH audits are unlawful because HHS's carriers audit providers to ensure that reimbursement complies with the Medicare Act, and Section 9(a)(2) of the IG Act prohibits the IG from exercising agency "program operating responsibilities." Nothing in that Section, however, precludes the IG from exercising her mandated functions whenever her investigatory authority overlaps with that of the carrier.

Section 9(a)(1) immediately transferred into the newly-created inspector general offices numerous preexisting investigative offices. 5 U.S.C. App. 9(a)(1), at

32. Section 9(a)(2), in turn, provides that "[t]here shall be transferred * * * to the office of Inspector General * * * such other offices or agencies, or functions, powers, or duties thereof, as the head of the establishment involved may determine are properly related to the functions of the Office * * *, except that there shall not be transferred to an Inspector General under paragraph (2) program operating responsibilities." 5 U.S.C. App. 9(a)(2), at 32-33. As is clear from the plain text, Section 9(a)(2)'s reference to "program operating responsibilities" imposes a limit only on the agency head's ability to "transfer[] to an Inspector General under paragraph (2)" additional offices or functions beyond those already conferred by Congress. 5 U.S.C. App. 9(a)(2), at 33. It is inconceivable that Congress, which created the OIG precisely because of the failure of agencies to combat fraud and abuse effectively, would then make the IG's authority to investigate waste depend upon the agency's own ability to detect it.

The PATH initiative is undertaken pursuant to HHS OIG's independent authority to detect and prevent fraud. The carriers have not relinquished their powers to conduct routine compliance audits, nor has the Secretary transferred that function to the IG.

The 1989 Opinion of the Office of Legal Counsel (OLC) upon which petitioners rely, Pet. 13-14 (citing 13 Op. Off. Legal Counsel 54 (1989)), explicitly disclaims any application to investigations such as the PATH audits. The OLC opinion both begins and concludes by stressing that "[t]he significant investigat[ory] authority granted to Inspectors General * * * includes the authority to investigate recipients of federal funds * * * to determine if they are complying with federal laws and regulations." 13 Off. Legal Counsel at 54; *id.* at 66 (same). OLC expressly limited its opinion to "in-

vestigations pursuant to statutes that provide the Department with regulatory jurisdiction over private individuals and entities *that do not receive federal funds*," *id.* at 54 (emphasis added), such as the Fair Labor Standards Act of 1938 and Occupational Safety and Health Act of 1970, "which impose restrictions on individuals and entities * * * who are not * * * recipients of federal funds distributed by the Department," *id.* at 55-56. In fact, the OLC opinion specifically defined the term "regulatory investigation"—a phrase petitioners attempt to invoke here—as "investigations [that] generally have as their objective regulatory compliance by private parties," as distinguished from investigations aimed at eliminating "waste and fraud among * * * recipients of federal funds." *Id.* at 54 n.1.

The legislative history of the IG Act also is fully consistent with the court of appeals' decision. Petitioners cite a House Report that states that the IGs will not have direct responsibility for conducting audits such as those "conducted by USDA's Packers and Stockyards Administration in the course of its regulation of livestock marketing" or Department of Labor investigations aimed at "enforcing the Fair Labor Standards Act." Pet. 4 (quoting H.R. Rep. No. 584, 95th Cong., 1st Sess. 12-13 (1977)). The salient characteristic of those two examples is that they, like the investigations discussed in the OLC opinion, concern the enforcement of regulatory schemes that, unlike benefit programs, do not involve the potential for "waste of federal funds." See 13 Op. Off. Legal Counsel at 60-61 (discussing House Report).

Moreover, the legislative history of the IG Act specifically endorses the kind of investigative initiative undertaken by the HHS OIG here. The Senate Report commended the HEW Inspector General's "Project

Integrity," in which the IG "spearhead[ed] a nationwide effort to deal systematically with Medicaid fraud." S. Rep. No. 1071, *supra*, at 8. "Using computer screening to identify doctors and pharmacists performing services which appeared unusual when compared with certain norms," the IG had identified over 1000 cases warranting criminal or administrative action. *Ibid.* That initiative, which Congress held up as an example, is indistinguishable in salient respects from the present PATH audits.

b. Petitioners also argue that the court of appeals' decision conflicts with *Burlington Northern Railroad Co.* v. *Office of Inspector General, Railroad Retirement Board*, 983 F.2d 631 (5th Cir. 1993), and *Truckers United for Safety* v. *Mead*, 251 F.3d 183 (D.C. Cir. 2001). Pet. 17-24. That is not correct.

Burlington Northern did not endorse petitioners' construction of the IG Act. As the Fifth Circuit explained in the subsequent case of *Winters Ranch Partnership* v. *Viadero*, 123 F.3d 327 (1997), *Burlington Northern* held only that an agency may not "relinquish its own performance of [a] function" such that there is an effective "transfer of function" that would be precluded by Section 9(a)(2). *Id.* at 334-335 (explaining that, in *Burlington Northern*, the Railroad Retirement Board had "never exercised its statutory duty" to investigate railroad companies' payment of taxes to an employee insurance account, and the IG "assumed the agency's primary duty" in its place, including adopting a plan to "conduct[] regular tax collection audits of substantially all major railroads on a continuing long-term basis"); accord *United States* v. *Chevron U.S.A., Inc.*, 186 F.3d 644, 648 (5th Cir. 1999) (*Burlington Northern* inapplicable where agency "continues to keep

the relevant records" and "subpoenas do not displace any agency responsibilities").

Petitioners do not suggest that the Medicare carriers have "relinquish[ed their] own performance of [the audit] function." *Winters Ranch*, 123 F.3d at 334. Nor could they. The carriers continue to have primary responsibility for ensuring that Medicare providers are entitled to the reimbursement they claim. The PATH initiative covers only a specified period of time in the past, is directed at a small subset of providers (teaching hospitals), and focuses only on two discreet issues that the HHS OIG has reason to believe were susceptible to large-scale fraud and abuse.

The D.C. Circuit's decision in *Truckers United for Safety* is similarly inapposite. There, the IG was engaged in a joint program with the Office of Motor Carriers within the Department of Transportation "to create a greater deterrence to motor carrier violations of * * * Safety Regulations." 251 F.3d at 187. The target companies received no federal funds, and the IG was not "engaged in an investigation relating to abuse" of DOT's programs. *Id.* at 189. Like the safety investigations at issue in the 1989 OLC opinion, the DOT IG's investigation was merely "to determine whether individual trucking companies were complying with federal motor carrier safety regulations." *Ibid.* *Truckers United* has no application to the investigation of fraud and abuse by recipients of federal Medicare funds.[2]

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[2] It also is not clear that *Truckers United* remains good law on its own facts. Congress subsequently enacted legislation to clarify that the DOT IG can investigate any fraud on the agency by an entity regulated by DOT. Act of Oct. 9, 1999, Pub. L. No. 106-69, 113 Stat. 1013; Motor Carrier Safety Improvement Act of 1999, Pub. L. No. 106-159, § 228(a) and (b), 113 Stat. 1773. The D.C. Cir-

2. Petitioners also argue that the court of appeals erred in concluding that the IG's interpretation of the Medicare Act and regulations as requiring physical presence of an attending physician was not subject to judicial review at this time. Pet. 24-29. That contention also lacks merit.

One of several "prerequisite[s]" for judicial review under the APA is that the challenged conduct constitute "final agency action." *Dalton* v. *Specter*, 511 U.S. 462, 469 (1994); 5 U.S.C. 704. "[T]he action must mark the 'consummation' of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature"—and "must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett* v. *Spear*, 520 U.S. 154, 177-178 (1997) (citations omitted).

In *Standard Oil*, *supra*, the Court held that the FTC's issuance of an administrative complaint, which alleged that the Commission had "reason to believe" that the respondents were engaged in unfair trade practices, was not "final agency action." 449 U.S. at 234, 238. The decision to investigate served only to initiate the matter; it was not a definitive ruling, and had no legal force or practical effect on Standard Oil's day-to-day operations other than the costs and disruptions of the proceeding, which were similar to those that accompany any major litigation. *Id.* at 241-242.

Based on those same considerations, the court of appeals correctly held that the HHS OIG's decision to undertake a PATH audit is not final agency action. Pet. App. 23a-29a. Moreover, in this case, unlike in *Stan-*

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cuit declined to address whether the DOT IG could, in the future, undertake similar investigations in light of this new statutory authority. *Truckers United*, 251 F.3d at 191-192.

dard Oil, the IG's decision to undertake a PATH audit does not even amount to a threshold determination of "reason to believe" that petitioners are in violation of Medicare law, let alone any definitive determination of petitioners' liability. Indeed, it is still quite uncertain whether any enforcement action will be taken against petitioners. In the past, in a third of the then-completed PATH audits, "no enforcement action was taken." C.A. App. A251-A252; *Physicians at Teaching Hospitals (PATH) Audits: Hearing Before a Subcomm. of the Senate Comm. on Appropriations*, 105th Cong., 1st Sess. 396 (1998) (PATH reviews have been terminated at institutions where few errors have been identified during audits).

The IG's initiation of an audit does not determine any rights or obligations or have legal consequences for petitioners' primary conduct or day-to-day operations. "[A]n administrative investigation adjudicates no legal rights." *SEC* v. *Jerry T. O'Brien, Inc.*, 467 U.S. 735, 742 (1984). Even assuming that the IG refers petitioners for proceedings to assess administrative penalties or commencement of a False Claims Act case, petitioners will have ample opportunity to raise all their arguments as defenses to an enforcement action. "[T]he extent to which the respondent may challenge the complaint and its charges proves that the averment of reason to believe is not 'definitive' in a comparable manner to the regulations in *Abbott Laboratories* [v. *Gardner*, 387 U.S. 136 (1967)]." *Standard Oil*, 449 U.S. at 241.

The court of appeals' decision also is consistent with the decisions of other courts that have dismissed pre-investigation challenges to the PATH initiative on ripeness and finality grounds. *Association of Am. Med. Colls. (AAMC)* v. *United States*, 217 F.3d 770, 781 (9th

Cir. 2000); *Temple Univ.* v. *Brown*, No. 00-CV-1063, 2001 WL 185535 (E.D. Pa. Feb. 23, 2001), aff'd *sub nom. Temple Univ.* v. *Rehnquist*, No. 01-3862, 2002 WL 31012237 (3d Cir. Aug. 20, 2002) (46 Fed. Appx. 124) (not precedential); *Greater N.Y. Hosp. Ass'n* v. *United States*, No. 98 Civ. 2741 (RLC), 1999 WL 1021561, at *5-*7 (S.D.N.Y. Nov. 9, 1999). As the Ninth Circuit succinctly stated, "[a]n investigation, even one conducted with an eye to enforcement, is quintessentially non-final as a form of agency action." *AAMC*, 217 F.3d at 781.

Abbott Laboratories, upon which petitioners rely (Pet. 24-26), is not to the contrary. That decision involved final agency action in the form of formally issued regulations that forced drug manufacturers to risk serious penalties for noncompliance, or undertake costly changes in labeling and advertising materials. See *Standard Oil*, 449 U.S. at 242. Petitioners make no claim that the HHS OIG's decision to undertake a PATH audit, which focuses exclusively on past conduct (billings prior to 1996), has any impact on petitioners' present or future primary conduct. Petitioners are simply required to cooperate with the audit, an entirely reasonable aspect of participating in receiving large amounts of federal funds under the vast Medicare program. *Standard Oil* makes clear that the initiation of an investigation—even one in which the cost and burden of responding is "substantial"—does not qualify as the kind of immediate impact on day-to-day activities that will satisfy the *Abbott Laboratories* finality requirement. See *id.* at 243 (such costs are no more "than the disruptions that accompany any major litigation"). "[T]he expense and annoyance of litigation is part of the social burden of living under government." *Id.* at 244. Finally, even if the HHS OIG's initiation of the investigation constituted final agency action, neither that

initiation nor the IG's interpretation of the Medicare Act and regulations would be ripe for judicial review at this stage. See, *e.g.*, *Ohio Forestry Ass'n* v. *Sierra Club*, 523 U.S. 726, 732-737 (1998).[3]

b. Even if the IG's determination of how to conduct her investigation constituted final agency action and were ripe for review, the decision whether and how to investigate recipients of Medicare payments is one "committed to agency discretion by law," 5 U.S.C. 701(a)(2), and therefore not subject to judicial review. Pet. App. 32a (Ambro, J., concurring); *Webster* v. *Doe*, 486 U.S. 592, 599-600 (1988).

The IG Act confers on the IG authority "to make such investigations and reports relating to the administration of the programs and operations of [HHS] as are, *in the judgment of the Inspector General, necessary or desirable.*" 5 U.S.C. App. 6(a)(2), at 19 (emphasis added). See *NASA* v. *FLRA*, 527 U.S. 229, 239 (1999) (Section 6(a)(2) confers "discretion" on the

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[3] Petitioners also err in asserting (Pet. 27) a conflict between the court of appeals' decision and the D.C. Circuit's decisions in *General Electric Co.* v. *EPA*, 290 F.3d 377 (2002), and *Mountain States Tel. & Tel. Co.* v. *FCC*, 939 F.2d 1035 (1991). Those decisions did not involve instigation of an IG audit but simply permitted judicial review when a regulated entity was required to comply with a new regulation adopted by the agency. *General Elec.*, 290 F.3d at 381-382 (review of EPA Guidance Document that "purports on its face to bind both applicants and the Agency" with respect to clean up and disposal of PCB waste); *Mountain States*, 939 F.2d at 1038-1039 (review of "new accounting rules" adopted by the FCC after notice and comment). Moreover, in each case, the D.C. Circuit noted that the relevant judicial review provisions *required* petitioners to seek judicial review within sixty days of the new rule's adoption. See *General Elec.*, 290 F.3d at 381 (Toxic Substances Control Act, 15 U.S.C. 2618(a)(1)(A)); *Mountain States*, 939 F.2d at 1040 (Hobbs Act, 28 U.S.C. 2344).

Inspectors General in the conduct of their investigations).

The language of Section 6(a)(2) is similar to the grant of discretion that barred APA review in *Webster*, *supra*. See 486 U.S. at 600 (statutory language authorizing the Director of Central Intelligence to terminate an employee "whenever the Director 'shall deem such termination necessary or advisable in the interests of the United States,'" foreclosed APA review). Section 6(a)(2) of the IG Act similarly reflects Congress's intent to foreclose review. Other provisions of the Act reinforce that conclusion. See, *e.g.*, 5 U.S.C. App. 3(a), at 13 (prohibiting agency head from interfering with IG audit, investigation, or subpoena), 5 U.S.C. App. 6(a)(4), at 19 (granting IG broad subpoena power to obtain evidence "necessary in the performance of the [IG's] functions").

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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IN THE

Supreme Court of the United States

THE UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY, and UNIVERSITY PHYSICIAN ASSOCIATES OF NEW JERSEY,

Petitioners,

v.

DARA CORRIGAN, Acting Inspector General, United States Department of Health and Human Services,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

REPLY BRIEF

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RULE 29.6 STATEMENT

Petitioners' corporate disclosure statement was set forth at page *ii* of the Petition for a Writ of Certiorari, and there are no amendments to that statement.

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REPLY TO BRIEF IN OPPOSITION

Pursuant to Supreme Court Rule 15.6, Petitioners reply to the following new points raised in the Brief for the Respondent in Opposition ("Opp. Br.").

1. Respondent's Opposition is based on the false premise that the Inspector General ("IG") of the Department of Health and Human Services ("HHS") is conducting an "audit or investigation of potential fraud or abuse" of Petitioners as recipients of Medicare funds. (Opp. Br. at 14). Before the litigation, and Petitioners' challenge to the HHS-IG's authority to conduct routine compliance audits, the IG made it clear that the nationwide audits of all academic medical centers were aimed at "*compliance* with Intermediary Letter 372 [teaching physician billing regulation]." Verified Cplt., Exh. P at 1 (C.A.A. 183) (emphasis added). Also before the litigation, the IG informed Petitioners that she did not suspect fraud by their teaching physicians. *Id.* at ¶ 73 (C.A.A. 67). After this challenge to the IG's authority to conduct routine compliance audits commenced, the IG began describing her audit as an alleged fraud investigation in an attempt to create authority where plainly none exists. This is an implicit concession that the IG lacks authority to do compliance audits and must refashion the audit as a fraud investigation to support her assertion of authority.

2. The only section of the IG Act of 1978 upon which Respondent relies does not support her position. Under the Inspector General Act of 1978, 5 U.S.C.A. app. 3 § 6(a)(2), the IG has broad discretion to "make . . . investigations and reports relating to the administration of the programs and operations of [HHS]." The authority granted here is to make investigations for the purpose of submitting reports to the

Secretary and Congress about the operations of the department. The authority granted by § 6(a)(2) is the same as was granted by § 204(d)(A) of the previous IG Act of 1976, which detailed the procedure, timing, and content of the HHS-IG's reports to Congress and the Secretary. Pub. L. 94-505, Title II, 90 Stat. 2431-32 (1976). This case is not about the IG's authority to conduct investigations for the purpose of making reports to the Secretary and the Congress regarding the operations of the Medicare program.

3. This case is instead about the IG usurping the authority specifically granted by Congress to the local Medicare carriers to conduct routine compliance audits. 42 U.S.C. § 1395(u)(a)(1)(A)(C). This specific grant of authority to the carriers trumps the generic language, upon which Respondent relies, of the IG Act of 1978 to "conduct, supervise, and coordinate audits and investigations relating to [HHS] programs." (Opp. Br. at 4). Significantly, the Respondent's Opposition fails to address the Petitioners' central argument on this issue, namely, the specific statutory delegation by Congress of the audit compliance function to the carriers.

4. Respondent makes the highly formalistic argument that *Burlington Northern R.R. v. Office of Inspector General, R.R. Ret. Bd.*, 983 F.2d 631 (5th Cir. 1993) is inapposite because the Centers for Medicare and Medicaid Services ("CMS") and its local carriers have not expressly and formally transferred the authority delegated to them by Congress to the IG, in contravention of Section 9(a)(2) of the IG Act of 1978. (Opp. Br. at 14). That argument is beside the point. The IG may not conduct routine compliance audits because, as the D.C. Circuit and the Fifth Circuit have recognized, such audits do not fall within the authority

granted to IGs by Sections 4 and 6 of the IG Act. To ensure that the limitation is respected, Section 9(a)(2) of the IG Act also prohibits the agency from transferring *its own* routine compliance authority to the IG. The statute therefore prohibits an IG from assuming routine compliance functions even if the agency wanted the IG to do so. The fact that the IG in this case has de facto usurped that function without even the fig leaf of a "transfer" of authority from the agency makes that usurpation worse, not better.

5. Petitioners, recipients of Medicare funds, do not argue that they cannot be audited for routine compliance or for fraud. Instead, this dispute is about which federal agency has the statutory authority to audit Petitioners for compliance. Congress has directed the Secretary to make the Medicare carriers the exclusive agents to perform routine compliance audits and has restricted the IG of HHS to "auditing and investigating [HHS]," *United States Dep't of Justice v. Federal Labor Relations Auth.*, 39 F.3d 361, 368 (D.C. Cir. 1994), and to conducting fraud investigations. "Congress intended the Inspector General to be an objective official free from general regulatory responsibilities who investigated the employees and operations of the Department, as well as its contractors, grantees and other recipients of federal funds, so as to root out waste and fraud." Authority of the Inspector General to Conduct Regulatory Investigations (Preliminary Opinion), 13 Op. O.L.C. 63, 1989 OLC LEXIS 4 (March 9, 1989).

6. The 1989 Opinion of the Office of Legal Counsel recognizes the authority of an IG to investigate recipients of Federal funds for fraud. *Id.* at *17. Petitioners make no challenge to that authority. Nor do Petitioners challenge the authority of the federal government to conduct routine

compliance audits of their Medicare operations. But these distinct functions have been assigned by Congress to two different agencies: the IG has authority to investigate recipients of Medicare funds for fraud, while the Medicare carriers have the exclusive authority to conduct routine compliance audits.

7. Even assuming that resort to legislative history is appropriate here when the statutory language and the structure established by Congress are clear, *Household Credit Servs., Inc. v. Pfenning*, 124 S. Ct. 1741, 1746-47 (2004), the legislative history cited by Respondent merely confirms that Congress intended the IG of HHS to conduct fraud investigations. (Opp. Br. at 12-13) (noting Senate Report commendation of HHS-IG for spearheading "'nationwide effort to deal systematically with Medicaid *fraud*'") (emphasis added). Respondent does not cite to any reference in that legislative history mentioning the conduct of routine compliance audits by the IG.

8. Respondent's attempt to distinguish *Burlington Northern*, 983 F.2d 631 (5th Cir. 1993) and *Truckers United for Safety v. Mead*, 251 F.3d 183 (D.C. Cir. 2001) is unpersuasive. Respondent argues that *Burlington Northern* is unlike this case because there the agency "never exercised its statutory duty," (Opp. Br. at 13), while here the carriers "continue to have *primary* responsibility for ensuring that Medicare providers are entitled to the reimbursement they claim." (*Id.* at 14) (emphasis added). But Congress did not grant concurrent authority to the IG and the carriers to perform that function; it granted exclusive authority to the carriers.

9. Respondent's effort at distinguishing *Truckers United* is even less convincing. According to Respondent, "*Truckers United* has no application to the investigation of fraud and abuse by recipients of federal Medicare funds." *Ibid.* (footnote omitted). But, as demonstrated above, the IG's own language, before the challenge to her authority, characterized the PATH audits, specifically as they pertained to Petitioners, as compliance efforts, not fraud investigations. That this case involves recipients of federal funds while *Truckers United* did not is not a fact relevant to the rationale of that decision. There, the Court of Appeals held the IG's effort "to determine whether individual trucking companies were *complying* with federal motor carrier safety regulations," 251 F.3d at 187 (emphasis added), was *ultra vires* and unauthorized by the IG Act of 1978. The IG was not attempting to *enforce* the regulatory safety regulations against members of the public; he sought to assist the regulatory agency in auditing whether the public was complying with them. *Id.* at 184 ("the Office of Motor Carriers . . . initiated compliance review investigations into appellants' record keeping practices [and sought the IG's assistance] to obtain appellants' business records"). The D.C. Circuit's ruling that such actions are prohibited by the IG Act of 1978 applies with at least equal force to the IG's unilateral effort in this case to audit Petitioners' compliance with a Medicare billing regulation. There is nothing in the language of the IG Act of 1978 or its structure to suggest a different ruling in the case of recipients of federal funds. Indeed, the specific grant of congressional authority to the carriers to perform the compliance function makes this case an even stronger one for denying the IG the authority to do compliance audits.[1] And while the 1989

1. In *Truckers United*, the Court of Appeals specifically rejected the argument, advanced by Respondent (Opp. Br. at 14 n.2), that the 1999 legislation cited by Respondent that specifically granted

(Cont'd)

OLC opinion noted that it was not analyzing a situation involving the recipients of federal funds, it did clearly reject the suggestion, made by the HHS-OIG at the time, that HHS was somehow exempt from the basic "separation of powers" principles embodied in the IG Act. *See* OLC op. at *16 n.13. Respondents' interpretation of the Act would entirely nullify the distinction between the IG and the agency itself for all of the many federal programs (Medicare, Medicaid, Social Security, etc.) that exist principally to distribute federal funds. That is plainly not what Congress intended.

10. While not central to Petitioners' challenge to the IG's statutory authority to do routine compliance audits, certain aspects of Respondent's statement of facts require correction. Whether or not the "'overwhelming majority' of regional carriers had consistently read [the regulatory language] to require the attending physician's physical presence when a resident performed a service'" (Opp. Br. at 5)—a doubtful proposition[2]—the evidence is uncontradicted in this case that Petitioners' carrier did not communicate that to them as the billing standard.

(Cont'd)
additional authority only to the IG of the Department of Transportation ("DOT") repudiated the *Burlington Northern* doctrine and retroactively authorized the 1998 IG compliance audits undertaken by the IG of DOT. While the Court of Appeals "declined to address whether the DOT IG could, in the future, undertake similar investigations in light of this new statutory authority," (Opp. Br. at 14-15 n.2), it reversed the district court on the issue of retroactive authorization argued by Respondent here. 251 F.3d at 191-92.

2. The PATH Overview cited by Respondent refers to 6 of the 25 Medicare Part B carriers in existence in 1996 as having such a clear standard (C.A.A. 320-21). *See Medicare & Medicaid Guide* (CCH) § 44, 641 (listing number of Medicare carriers in 1996). Twenty-four (24) percent is hardly an "overwhelming majority."

11. The Medicare carrier guidance that Respondent relies upon to establish Petitioners' knowledge of the standard the OIG wishes to employ in the audits was issued by the Pennsylvania carrier and not that for New Jersey. After the Pennsylvania carrier also became the New Jersey carrier on January 1, 1989, the publication was not reissued to New Jersey providers such as Petitioners. The IG determination of notice to Petitioners is based upon decennial indices put out by the carrier in 1989 and 1990 (after its territory was expanded to include New Jersey) that contains a listing (in single-spaced, double columns) of all publications put out over the period 1980-90, including the carrier guidance first published in 1982 to non-New Jersey providers that had not been re-sent to the New Jersey providers such as Petitioners after 1989. (C.A.A. at 256-67, 288-98, and 302-07).

12. Even if Petitioners' carrier had communicated that standard, the fact, conceded by Respondent (Opp. Br. at 3 and n.1) and the Court of Appeals (Cert. Pet. App. 8a), that the Secretary's regulation did not contain the requirement that residents treat patients "in the presence of a teaching physician" would have entitled Petitioners to bill in compliance with the Secretary's regulation, and not follow the carrier's stricter interpretation. While carriers, as noted above, are authorized by Congress to conduct compliance audits, only the Secretary is vested by Congress with authority to promulgate and interpret substantive Medicare regulations. 42 U.S.C. § 1395(g) (West Supp. 2002). In billing Medicare, Petitioners properly complied with the Secretary's then-existing regulation and their carrier's interpretation.

13. Respondent's implied charge of bad faith by Petitioners is unwarranted. (Opp. Br. at 7). Petitioners originally agreed to employ an independent auditor to do a PATH audit upon the expressed understanding that the OIG would utilize the billing standard in the Secretary's regulation and communicated to them by their carrier, and that they understood to be in effect when they submitted their bills. Petitioners expressly reserved their right to withdraw from the self-audit and challenge any aspect of it. (C.A.A. 538-40). When the IG refused to apply what Petitioners maintain is the correct standard, and directed the independent auditor to use a different standard (C.A.A. 539-40), Petitioners sued to enjoin the audit.

14. This case does not involve a "risk that Medicare providers will bill the program twice for the same services." (Opp. Br. at 2). Under Part A of the Medicare program, hospitals submit annual costs reports listing their costs of goods and services and Medicare reimburses them the allowable costs for such goods and services, including the direct costs of residents in training ("GME") and the indirect costs associated with having residency teaching programs ("IME"). 42 C.F.R. 412, 413.86. Separately, under Part B of Medicare, physicians who practice at such hospitals and teach in the approved residency programs may bill Medicare for *their* services to Medicare patients in such hospitals. 42 C.F.R. 414, 415. The GME and IME reimbursements by Medicare to hospitals are distinct and separate from reimbursements to teaching physicians for *their* services to patients. *Compare* 42 C.F.R. 412, 413.86 *with* 42 C.F.R. 414, 415. If teaching physicians are employees of the hospital and assign to the hospital their right to bill for their services for Medicare patients, the hospital will be reimbursed the Part B payment that would otherwise be made to the

physician. Otherwise, hospitals do not bill, and are not reimbursed by Medicare, for the services of their teaching physicians; teaching physicians do not bill, and are not reimbursed, for GME and IME costs.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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IN THE

Supreme Court of the United States

THE UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY, AND UNIVERSITY PHYSICIAN ASSOCIATES OF NEW JERSEY,

Petitioners,

v.

DARA CORRIGAN, Acting Inspector General, United States Department of Health and Human Services,

Respondent.

On Petition For a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF ASSOCIATION OF AMERICAN MEDICAL COLLEGES IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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INTEREST OF THE *AMICUS CURIAE*

The Association of American Medical Colleges (AAMC) respectfully submits this brief *amicus curiae* in support of the Petition for Certiorari in this matter. Pursuant to Supreme Court rule 37.2(a), counsel for the parties have consented to the filing of this amicus brief, and their letters of consent have been filed with the Clerk of the Court.[1]

The decision below, in direct conflict with decisions of two other courts of appeals, approved the performance of routine program audits by the Office of Inspector General of the U.S. Department of Health and Human Services (OIG). That decision undermines the independence of Inspectors General and defeats the principal purpose of the Inspector General Act of 1978.

Founded in 1876, the Association of American Medical Colleges (AAMC) represents 126 accredited medical schools, nearly 400 major teaching hospitals and health systems, more than 105,000 faculty in 98 academic and scientific societies, and the nation's 66,000 medical students and 97,000 residents. Dozens of AAMC member institutions have been subjected to *ultra vires* audits by OIG in its "Physicians at Teaching Hospitals" ("PATH") initiative, which is at issue in this case, and are deeply concerned with the unauthorized expansion of OIG's duties. This Court should affirm OIG's unique role as an independent reviewer of government programs.

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[1] Pursuant to Rule 37.6, amicus states that no counsel for any party authored this brief in whole or in part, and no person or entity other than the *amicus curiae* made a monetary contribution to the preparation or submission of this brief.

SUMMARY OF THE ARGUMENT

The Inspector General Act of 1978 was enacted to address one of the intractable questions of public administration: "Who watches the watchers?" The Act's central premise is that government programs should be reviewed by auditors and investigators who are independent and free of conflicts of interest. The explicit goal of the legislation is to create "independent and objective units" of government. 5 U.S.C. app. 3 § 2. To ensure that independence, Congress adopted an organizational structure that sets Inspectors General apart from agency bureaucracies, and specifically barred agencies from transferring "program operating responsibilities" to the new units. *Id.* at § 9(a)(2).

Almost twenty years after the Act was adopted, OIG violated these congressional restrictions when it initiated the PATH audits of physician billing at the nation's teaching hospitals. Without having information that specific physician groups or hospitals had mischarged the Medicare program for teaching physician services, OIG's blanket approach to the PATH audits exceeded the scope of its powers as defined by Congress. In design and in execution, the PATH audits were indistinguishable from routine Medicare billing audits that are performed on a daily basis by 46 Medicare contractors around the country. No matter how praiseworthy OIG's intentions may have been, and no matter how many dollars the PATH audits may have won in settlements, the effort fundamentally defeated Congress' purpose in establishing the Inspectors General.

The decision below also cannot be reconciled with decisions of two other courts of appeals that have enforced the congressional ban on program auditing by Inspectors General. *See Burlington Northern R.R. Co. v. Office of Inspector General,* 983 F.2d 631 (5th Cir. 1993); *Truckers United for Safety v. Mead,* 251 F.3d 183 (D.C. Cir. 2001). The decision below particularly warrants this Court's review because of the massive size of the Medicare and Medicaid programs, and the

dependence of health care providers and their patients on those programs. In that context, the erosion of Inspector General independence approved by the Third Circuit will have a disproportionately large impact.

By its participation in this case, AAMC in no way endorses or excuses overcharging of the Medicare program. The PATH initiative identified billing errors – mostly inadvertent ones caused by decades of confusing government pronouncements. In so doing, however, the OIG sacrificed the independence and objectivity that are the principal reasons for its existence.

ARGUMENT

I. Inspector General Independence Was An Essential Purpose of the 1978 Act

The Inspector General Act was born of a deep congressional frustration with the lack of independence of federal auditors. The House Report on the legislation recited a catalogue of government audits that had been hamstrung by self-protective superiors (124 CONG. REC. 10402 (Apr. 18, 1978)):

> [I]nvestigators in some agencies are not permitted to initiate investigations without clearance from officials responsible for the programs involved. [One official] testified that he had been denied clearance to investigate allegations of wrongdoing on several occasions: in one of these cases, according to his testimony, a later investigation by another law enforcement agency resulted in 22 indictments.
>
> [He] also testified that he had been ordered to discontinue one investigation which had already been initiated: the subject of that investigation, who was suspected of embezzling $10,000, subsequently became a fugitive.

> A supervisory investigator for the Small Business Administration testified that an office inspection program which might have resulted in earlier detection of irregularities in SBA's Richmond office had been terminated some years ago.

As the Office of Legal Counsel of the Justice Department observed in a 1989 interpretation of the statute, Congress found that "existing audit and investigative units were inadequate to deal with this problem [of waste, fraud and abuse] because they reported to, and were supervised by, the officials whose programs they were to audit and investigate." 13 U.S. OP. OFF. LEGAL COUNSEL 54, 58 (1989) ("OLC Opinion"). What was needed, Congress concluded, was a corps of agency auditors and investigators who were independent of narrow bureaucratic agendas. *See* S. REP. NO. 195-1071, at 7 (1978), *reprinted in* 1978 U.S.C.C.A.N. 2676, 2682.

Congress sought to ensure that independence by imposing several structural protections on the fourteen cabinet-level departments covered by the Act, plus seventeen other federal agencies authorized to have Inspectors General. *See* 5 U.S.C. app. 3 § 11(2). Each of those thirty-one Inspectors General is appointed by the President, with the advice and consent of the Senate. *Only* the President may remove an Inspector General from office, and he must provide to Congress a formal explanation for such a removal, a unique procedure in the entire federal government. 5 U.S.C. app. 3 § 3(a).

The Inspector General is responsible *only* to the head of her agency, not to any intermediate official. *Id.* No one - not even the head of the agency - has the power to restrict any investigation or audit initiated by the Inspector General. *Id.* Moreover, the Inspector General may submit reports directly to Congress without approval by the head of her agency, whose sole right is to review and comment on that report. *Id.*

at § 5(a), (b). *See generally* Dan W. Reicher, Note, *Conflicts of Interest In Inspector General, Justice Department, and Special Prosecutor Investigations of Agency Heads*, 35 STAN. L. REV. 975, 984-85 (1983).

Even with these structural protections, Congress feared that Inspector General independence could be compromised if the agency were able to gain control of the Inspector General's agenda, or if - as occurred in this case - the OIG assumed duties Congress specifically delegated to the federal agencies. Accordingly, the Act purposely bars the Inspector General from exercising "program operating responsibilities." 5 U.S.C. app. 3 § 9(a)(2). This prohibition ensures the Inspector General will not lose her critical eye towards the agency's own conduct by becoming enmeshed in the agency's routine operations. *See* H.R. REP. NO. 95-584, at 12-13 (1977) (Inspectors General have no responsibility for "audits and investigations constituting an integral part of the programs involved"). As the Justice Department emphasized when opining on this question in 1989 (OLC Opinion, *supra,* at 61):

> The purpose of creating an Inspector General was to have an official in the department who would not have responsibility for the operations of the department and would thus be free to investigate and criticize. If the Inspector General undertakes investigations under the department's regulatory statutes, he could not perform this role.

Within this structure of independence, OIG exercises the specific powers devolved on it by Congress (5 U.S.C. app. 3 § 4(a)):

1) To provide policy direction for and supervise audits and investigations of an agency's "programs and operations";

2) To review legislation, regulations, and proposals and make recommendations

concerning their impact on agency efficiency and on prevention and detection of fraud and abuse;

3) To recommend policies supporting those goals;

4) To conduct inter-governmental relationships to support those goals; and

5) To inform the agency head and Congress on all such matters.

These powers certainly contemplate OIG audits and investigations of non-governmental parties who participate in federal programs, such as health care providers who receive reimbursement from Medicare. Pet. App. 17a. But an Inspector General cannot exercise the agency's ordinary audit functions without compromising her own independence.

II. OIG's PATH Initiative Was a Routine Regulatory Audit

The PATH initiative emerged in 1996 when an OIG audit at a single academic medical center identified two Medicare billing issues: (a) the requirement for supervision of residents by teaching physicians, which for many years was a matter of confusion among Medicare officials and health care providers; and (b) recently-adopted standards for billing physician services for "evaluation and management" of Medicare beneficiaries.[2] Pet. App. 104a. With the result of that first audit in hand, the OIG did *not* employ its statutory powers to recommend further action by the thousands of

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[2] In 1992, Medicare implemented a standardized grid for classifying "evaluation and management" services provided by physicians, Pet. App. 116a, based on the nature of the patient examination, the complexity of medical decision-making, and severity of the problem presented. *See Physician at Teaching Hospitals (PATH) Audits: Hearings Before the Subcomm. of Senate Appropriations Comm.*, 105th Cong. 8 (Oct. 21, 1997) (statement of Michael Mangano, Principal Inspector General, Department of Health and Human Services).

auditors employed by contractors to the Medicare program. Instead, the OIG determined itself "to audit the major teaching hospital or faculty practice plan with each of the nation's 125 medical schools." GENERAL ACCOUNTING OFFICE, MEDICARE: CONCERNS WITH PHYSICIANS AT TEACHING HOSPITALS (PATH) AUDITS, at 12 (July 1998) ("GAO Report"); Julie Marquis, *UC Medical Centers Accused of Fraudulent Insurance Claims*, L.A. TIMES, Aug. 10, 1996, at A21 (Medicare official "said all 125 of the nation's medical centers that operate medical schools will be audited"). The OIG thereby undertook exactly the kind of routine program audit that is beyond its powers.

When asked to explain why it elected this "blanket approach," OIG stated to the General Accounting Office (GAO) that these teaching hospitals "had the greatest number of residents and received the most Medicare revenue." GAO Report, at 12. Notably, OIG did *not* suggest that it had any basis for believing that any targeted institution had either of the identified billing problems, nor did OIG suggest that it was undertaking a sampling of teaching hospitals so it might better gauge the nature of the problem.

Rather, as the Inspector General explained in 1996 correspondence, she elected to launch a "series of nationwide reviews." Pet. App. 104a. By July 1997, PATH reviews were "under way or planned at 49 institutions." GAO Report, at 12. As the GAO pointed out, OIG made no effort "to target institutions most likely in violation of teaching physician billing rules and [to] concentrate its efforts on these institutions." *Id.* at 13.

Both regulators and health care providers had long experienced confusion about the correct standards for teaching physician billing. Indeed, Medicare has described its pre-1995 statements on the subject as "vague," Pet. App. 111a, and "not consistently and clearly articulated . . . over a period of decades." *Id.* at 113a; 60 FED. REG. 63138 (Dec. 8, 1995).

Responding to complaints from AAMC and the American Medical Association, the Secretary of the Department of Health and Human Services asked the general counsel of that agency to set the substantive rules for OIG's PATH audits, which the general counsel did. Pet. App. 105a-117a. As a result of the general counsel's intervention, OIG agreed not to audit any institution whose Medicare contractor had – in OIG's opinion – failed to provide clear guidance on teaching physician billing. Pet. App. 115a.

OIG's "blanket approach" had predictably unfortunate consequences. The GAO Report examined the PATH audit at three institutions, including Dartmouth-Hitchcock Medical Center in New Hampshire. At Dartmouth, the PATH audit consumed ten months of effort before it was abandoned. It identified billing errors totaling $778 – "an amount [OIG] did not deem worthy of collecting" – and cost the institution "$1.7 million in compliance efforts and indirect costs." GAO Report, at 14. This result, the GAO observed diplomatically, "raises questions about the OIG's intent to audit all major teaching hospitals." *Id.* at 4.[3] OIG ultimately reduced the number of PATH audits because of "competing demands for its resources and determinations that some [Medicare contractors] did not provide clear communications regarding teaching physician physical presence rules." *Id.* at 13.

For this case, however, the salient feature of the PATH audits was their character as routine program audits. In a document summarizing the PATH initiative, the OIG wrote

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[3] The GAO's question is not answered by the simple observation that some PATH audits prompted significant repayment settlements. First, because of the threat of penalties authorized by the False Claims Act, those settlement amounts ordinarily doubled the amount of alleged overcharges. *See Thomas Jefferson Enters $12 Million Settlement Over Medicare Charges*, ASSOCIATED PRESS, Aug. 22, 1996. Moreover, the entities under audit felt compelled to settle because False Claims Act penalties "could have been financially devastating" even if liability applied to "relatively few false claims." GAO Report, at 20.

that "[t]he nationwide PATH reviews will focus on compliance with IL 372 [teaching physician billing instructions] and the appropriateness of service codes,"[4] subjects one would expect to see addressed in the course of routine audits. OIG was not investigating institutions it had reason to suspect were engaged in fraud or abuse. OIG was not evaluating the efficacy of Medicare's oversight and enforcement of rules for teaching physician billing. Nor was OIG developing policy recommendations for Congress or the Medicare program. OIG was simply conducting a blanket, routine program audit of physician billing by an entire sector of the health care industry. That is precisely the sort of audit that the Medicare program otherwise conducts every day, and precisely what Congress prohibited with § 9(b) of the Inspector General Act.

The Medicare program contracts with forty-six companies nationwide to perform audits of billing to Medicare by health care providers, and those contractors employ thousands of auditors to perform those tasks. 42 U.S.C. § 1395u(a)(1)(A); 42 C.F.R. § 421.201; *see Medicare Regulatory and Contracting Reform: Hearings Before the Health Subcomm. of House Ways and Means Comm.*, 108th Cong. 7 (Feb. 13, 2003) (testimony of Thomas Scully, Administrator, Centers for Medicare and Medicaid Services). Those regiments of Medicare auditors routinely review the coding and billing of teaching physician services on a post-payment basis, exactly as the OIG did in its PATH initiative. *See* MEDICARE PROGRAM INTEGRITY MANUAL §§ 3.4.4, 4.1 (describing postpayment review by Medicare contractors of coding and coverage issues in physician bills).

The PATH initiative's character as a regulatory audit is reinforced by two additional facts. First, as the GAO found in

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[4] HHS-OIG, PHYSICIANS AT TEACHING HOSPITALS (PATH): SUMMARY OF OIG INITIATIVE (Dec. 4, 1996).

its review, Medicare contractors had performed precisely this form of audit many times in the past. The second institution subjected to a PATH audit, for example, had experienced three such prior audits by a Medicare contractor in the preceding thirteen years. GAO Report, at 16. In fact, the Medicare contractor in Pennsylvania had conducted sixty-seven such prior audits statewide, according to OIG. PHYSICIANS AT TEACHING HOSPITALS (PATH) AUDITS HEARINGS 3.

Second, the substance of OIG's PATH work in no way reflected OIG's special statutory responsibilities, but were routine compliance reviews. OIG never criticized the Medicare program for providing confusing and inconsistent billing standards for teaching physicians, a critique that might be expected from the sort of fearless watchdog over the bureaucracy that the Inspector General Act contemplates. Indeed, OIG abandoned PATH reviews in mid-audit if the institution offered a settlement amount the OIG deemed sufficient, evidently unconcerned with whatever operational insights might be gleaned from a completed audit. GAO Report, at 19.

More disturbing was the OIG's failure to characterize accurately the problems it found. As the 1998 GAO report concluded:

- OIG reported to Congress that it had found several instances when teaching physicians billed for services when they were "on leave or out of town," but GAO was unable to confirm those assertions after reviewing OIG's workpapers. GAO Report, at 21.
- The HHS Inspector General told Congress in 1997 that in the first two PATH reviews the "huge majority" of upcoding errors were related to "multilevel" (more serious) upcoding. The GAO concluded that the Inspector General's claim was

> refuted by her own workpapers: "[T]he workpapers show the overwhelming majority of upcoding errors that were found at the two institutions involved one-level discrepancies. At one of these institutions, not only were few multilevel errors found by the OIG, but one physician accounted for about 70 percent of these." *Id.* at 21-22.

As these examples illustrate, little about the PATH initiative constituted an independent, objective view of government operations or suspected fraud. For its own reasons, OIG seized the opportunity to perform these routine regulatory audits, never casting a skeptical glance at the years of ambiguous government instructions on teaching physician billing that contributed mightily to the problem. *See* Pet. at 24-28.

III. This Court Should Resolve the Conflict Among The Lower Courts Over the Powers of the OIG.

The decision below squarely conflicts with the ruling by the U.S. Court of Appeals for the District of Columbia Circuit in *Truckers United, supra*. In that case, the Inspector General of the Department of Transportation conducted investigations of the possible "falsification" of safety records kept by trucking companies. 251 F.3d at 187. Those regulatory compliance reviews traditionally had been performed by the Office of Motor Carriers of the Federal Highway Administration. The D.C. Circuit found that the Inspector General had "merely lent his search and seizure authority to standard [Office of Motor Carriers] enforcement investigations," which was "beyond his authority" under the Inspector General Act. *Id.* at 189.

The court below attempted to distinguish *Truckers United* on the ground that the PATH initiative involved "fraud and abuse," while the truck-safety audits supposedly involved only "standard" enforcement investigations. Pet. App. 20a-21a. That attempted distinction is exactly backward. By any common understanding of the terms used in Section 4 of the

Inspector General Act, "fraud" and "abuse" plainly include the "falsification" of truck safety records at issue in *Truckers United*. 5 U.S.C. app. 3 § 4(a) (detailing responsibilities of all thirty-one Inspectors General concerning "fraud and abuse"). Equally, the OIG's activities in the PATH audit were entirely "standard," differing in no material way from the billing audits performed daily by the thousands of auditors employed by Medicare's contractors.

The decision below also conflicts with the Fifth Circuit's application of the Inspector General Act in *Burlington Northern, supra,* and *Winters Ranch P'ship v. Viadero*, 123 F.3d 327 (5th Cir. 1997). *Burlington Northern* declared that the Inspector General of the Railroad Retirement Board could not take over the Board's "regularly-scheduled, tax-compliance audits" of employers. If the Inspector General were to assume that function, the court held, his independence would be compromised: "[T]here would be no one, so to speak, to 'watch the watchdog.'" *Burlington Northern*, 983 F.2d at 643.

In *Winters Ranch*, the Fifth Circuit reviewed a plan to "spot check" price support compliance by six wool and mohair producers. 123 F.3d at 335. In contrast to the OIG's conduct of the PATH audits, when the USDA Inspector General found evidence of regulatory violations from those spot checks, "the IG turned this information over to the agency, which promptly conducted its own investigation." *Id.* Thus, the USDA Inspector General was truly evaluating the agency's performance, as well as surveying the compliance of a sample of wool producers, all within its statutory powers.[5]

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[5] *Winters Ranch* suggests in *dicta* that an Inspector General's independence cannot be compromised by performing a regulatory function unless the agency itself "relinquish[es] its own performance of that function." 123 F.3d at 334. That assertion is plainly wrong. An Inspector General's independence will be lost just as surely if she exercises duplicative "program operating responsibilities," as if she exercises program responsibilities that otherwise would be neglected. In both

Like *Burlington Northern*, the PATH audits closely resembled routine regulatory audits. Unlike *Winters Ranch*, the OIG did not merely "spot check" compliance and turn the results over to the agency to address.

The erroneous decision of the Third Circuit will have a disproportionately large impact because the HHS-OIG's office is so large, as is the Medicare program itself. In 2000, Medicare paid over $220 billion a year for health care services, or seventeen percent of all healthcare spending in the country. CENTERS FOR MEDICARE AND MEDICAID SERVICES, PROGRAM INFORMATION ON MEDICARE, MEDICAID, SCHIP AND OTHER PROGRAMS (2002). Respondent herself supervises over 1,500 employees, with a budget of $200 million. U.S. DEPT. OF HEALTH & HUMAN SERVICES, FY 2005 BUDGET IN BRIEF, *available at* http://www.hhs.gov/budget/docbudget.htm. Due to the sheer bulk of those programs, it is a particularly dangerous for the HHS-Inspector General to ignore congressional constraints on its powers, at the cost of its independence. The decision below also may signal to the other thirty Inspectors General that they may sacrifice their independence in pursuit of the short-term goals that may be achieved through routine program audits like the PATH initiative.

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situations, the OIG's independence and objectivity are the casualty of "be[ing] put in a position of operating the very programs they are supposed to oversee." William E. Fields & Thomas E. Robinson, *Legal and Functional Influences on the Objectivity of the Inspector General Audit Process*, 2 GEO. MASON IND. L. REV. 97, 108 (1993).

CONCLUSION

For the foregoing reasons, this Court should grant the Petition in this case.

Respectfully submitted,

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